THE PULSE

THE WHARTON HEALTH CARE JOURNAL

SPECIAL FEATURES

THE FUTURE OF HEALTH CARE IT
INTERVIEWS WITH MICROSOFT AND GOOGLE

RETHINKING EMERGING MARKET BUSINESS MODELS
A DEEPER LOOK AT INDIA

2030 HEALTH CARE
CRYSTAL BALL PREDICTIONS

SPRING 2009

WHARTON HEALTH CARE BUSINESS CONFERENCE

TABLE OF CONTENTS

THE PULSE IS AN INDEPENDENT, STUDENT-RUN JOURNAL

SPECIAL FEATURE: THE FUTURE OF HEALTH CARE IT

As a new administration begins, health care is once again at the forefront of national debate. While information technology is often hailed as the way to solve the inefficiencies of the U.S. health care system, attempts to use IT to automate and aggregate data — the same methods that revolutionized manufacturing, travel booking, and other industries — have not reached their full potential. So far, the health care system's complexity, varied stakeholders and insufficient funding have blunted advances.

But is the game about to change? Some of the brightest minds in the health care space think so. They feel that today's technologists, patients and providers have the interest and experience to take up the gauntlet.

The Pulse spoke with two organizations (Google and Microsoft) that are making large bets on how individuals and providers will interact in the future, and one individual (Jeff Goldsmith, noted health care futurist) who has been observing the pace of change for years. Our goal was to give readers a picture of why big players are breaking into a space that had been the province of specialist firms, and how that might change the ground rules.

Building a Common Platform for the Health Care Ecosystem

The Microsoft Health Solutions Group is spearheading the company's push into the health care terrain, which tackles both the software and personal health data sides of the equation. There are two main offerings: Amalga, an integrated hospital information system that includes everything from an electronic medical record to an imaging management system; and HealthVault, a website that allows individuals to store their health information in one place and integrate compatible data from pharmacy benefits managers, hospitals, and medical devices.

The Pulse spoke with Peter Neupert, who is heading this group, about the state of health care IT and Microsoft's current and long-term strategy.

User-Centered Personal Health Data

By contrast, Google Health is focused squarely on personal health data. Their aim is to integrate individual health information into a flexible, web-based tool that will serve as a platform for users to access third-party applications. This platform strategy is based on making it easy for users to upload information (via partnerships with physicians, hospitals, pharmacy benefits managers and others) and make use of it (by assembling a directory of third-party services that interoperate with the Google Health patient record).

Jerry Lin, a program manager, gives *The Pulse* insight into the power of this model, what it means for an individual's health care experience and where the Google Health record will go in the future.

Health Care Information Technology That Drives Better Outcomes

Jeff Goldsmith is a leading health technology futurist and has participated in most of the recent waves of information technology roll-out in health care. He discusses the past (and potential future) speed bumps that have slowed adoption of new systems, the importance of building software that is robust and simple, and the danger of building impressive systems that stay in silos instead of enhancing communications and clinical results. His vision? A Facebook for health care data that users control and providers can access.

S. Regan Murphy
WG'10

The Pulse: What is Microsoft's strategy and vision for HealthVault? For Amalga?

Peter Neupert: Microsoft is committed to improving health around the world with software innovation. Health is important in everyone's lives, and software solutions can enable people to make better and more informed behavioral decisions. With our products HealthVault and Amalga, we are trying to help people make the right decisions – whether you are a consumer or a health care provider.

Medicine is increasingly becoming a technology-driven environment. Computation is driving progress and data evidence across the industry. Whether it's growing a better understanding of how the body works or the discovery of new therapeutics and diagnostics, these technology systems are critical to accelerating improvements [in medicine]. That's why Microsoft is interested in providing specific solutions to help the health sector address its major challenges.

Pulse: There is huge room for improvement in health care information systems. How can software push us in the right direction?

PN: This is hard to talk about in the abstract, so let's dive into specifics. Zoom out from the health sector and you will find a complex ecosystem. I use the word "ecosystem" for a reason. Everything impacts everything else in a symbiotic environment. No one company, hospital, or vendor, can by itself change the system.

EMRs have a long legacy and history. They were developed to automate workflows that were paper-based and time-based. If you were to devise a medical workflow today, it would look very different. Imagine if you could have a constantly streaming dashboard of information about a patient and only have to interact or intervene when needed. This would greatly help health care workers to understand, prioritize and perform tasks they need to do. Many recognize that this type of approach can lead to more reliable care.

Whatever happens has to change the system, we cannot just perpetuate inefficiencies. There need to be a series of asynchronous and synchronous changes that move the paradigm of how we think of care. The private sector can help drive this innovation in partnership with policy reform. In particular, an organization like Wharton needs to focus on this trend and the areas where policy can support issues like reimbursement models. Without this policy reform, it

"Whatever happens has to change the system, we cannot just perpetuate inefficiencies."

will be very tough to drive change across the workflow and delivery pieces of the health care business.

Pulse: Your blog, Neupert on Health, comments on the importance of getting insurance companies to innovate. How do you envision the role of insurance companies changing, and what would you do if you were in their shoes?

PN: Insurance companies have two audiences they need to concern themselves with – consumers and health care providers (physicians/hospitals/health systems) – and understanding how the two interact. Insurers are well positioned to collect information that can be shared with physicians to enable new learning about patient care and how to improve day-to-day operations. The challenge lies in the longitudinal aggregation of data – a patient might be with Aetna one year, but United or Medicare another year. Payers also need to recognize how to use this information for the short-term customers that may return through work cycle changes, [and consider] how it could help their bottom lines in the future. Let me give you two examples.

The first: There is early evidence that health information data exchange between providers can save money for payers. The challenge for insurance companies, however, is how to work with providers to find mutual benefits in the process. In combination with the government, they must identify how to work together to subsidize and motivate these systems to exist – breaking down the barriers to adoption on the part of exchange participants.

The overall goal is to achieve the sharing of data that results in reduction of duplicate work, inappropriate testing and poor outcomes from diagnoses that are based on incomplete data.

The second: This example is more consumer-based. Value-based benefit design motivates consumers to be smarter about complying with health recommendations for chronic and pre-chronic conditions. Timely and accurate information can help to reduce the risk of patients reaching the acute chronic disease state.

As insurers look to extend and enrich relationships by communicating directly to consumers, what tools or incentives can they leverage to reach the right levels of motivation while scaling efforts to an appropriate price point for consumers? These goals may require systemic change.

Pulse: How can Microsoft help consumers help themselves?

PN: At Microsoft, we have a fundamental bias that "information matters." Whether electronically or in-person during a visit to the physician's office, every interaction in health care is centered around information: collecting data, applying business rules, communicating information back to the patient, generating and processing prescriptions, and delivering medicine.

Much of medicine is affected by miscommunication or inconsistent information. There is a lot of uncertainty in diagnosing, which software can help manage. As our knowledge base grows, software will become more critical. Our belief is that computationally-assisted tools and dashboards will make for better patient care decisions.

Pulse: With the advent of trends like medical homes, telemedicine, and receiving health information on our phones, how do you see things converging in the future?

PN: In five years health interactions will be more like travel interactions today versus [those of] 10 years ago. You don't just call a travel agent to find out availability anymore; you go online to find out pricing options available for wherever you want to travel in the world, to check in, to see what the line is like at security, and to check out special attractions at your destination. It is a self-service model that maps to a set of preferences for how one travels in a connected system.

As health care moves towards this model, delivery of care from professionals will migrate from solely institutional settings to "where you are." Tele-health, whether monitoring periodic things like hypertension or leveraging higher-end devices like defibrillators, enables care to be managed in the home in a much more cost effective manner. You will see much more research in the next few years about personal health devices, and this will dramatically change the way people manage their health and the way that health care is delivered.

Pulse: On a related note, what role does technology play in the standardization of health care delivery (e.g. evidence-based medicine)?

PN: I sit on the Institute of Medicine (IOM) roundtable for learning medical systems, sometimes called the Evidence Based Medicine (EBM) roundtable. Our

"In five years, health interactions will be more like travel interactions today versus [those of] 10 years ago."

discussions often focus on the fact that we generally only have access to data at a very high level, as a result of the fragmentation that prevails across our health delivery networks.

There are a few diseases where evidence-based protocols are very clear. However, there are many more diseases where they are not clear – where the information at hand does not provide rich enough clinical context to understand disease progression. The question is where will the data come from and how will we collect it so that we can improve our knowledge more quickly?

Generally, folks don't understand the inability of the system as a whole to deliver reliable, quality care.

PETER NEUPERT
CORPORATE VICE PRESIDENT, HEALTH SOLUTIONS GROUP, MICROSOFT CORP.

As Corporate Vice President for the Health Solutions Group at Microsoft Corporation, Peter Neupert is responsible for developing and driving the company's product and services strategy for health around the globe. In his position leading the Health Solutions Group, Neupert uses software to address business and clinical productivity issues across enterprise and research organizations with the Microsoft Amalga family of products, as well as the personal health needs of the individual consumer through Microsoft HealthVault.

Before rejoining Microsoft, Neupert served as President and Chief Executive Officer of Drugstore.com Inc. In 2000, his work at Drugstore.com earned him an Ernst & Young Entrepreneur of the Year award. Neupert holds an M.B.A. from the Tuck School of Business at Dartmouth College and a Bachelor's degree from Colorado College.

An interesting statistic I heard in a speech to the American College of Surgeons by Dr. Denis Cortese of the Mayo Clinic highlighted that even if we delivered the best care for every breast cancer case with today's results, you would deliver care that is reliable 80 percent of the time. That's the equivalent of two 747s crashing every week in the airline industry, and that's the best of the best.

Physicians want to do the right thing and a good database should help them do this. The key is to inform them real-time, without overwhelming them with data, so they have the tools they need to make decisions in a complex environment.

Pulse: Physicians today state they are bombarded with data (from patient test results to forms to phone calls, etc.) How would you handle improving the way physicians receive helpful, necessary information without overwhelming them?

PN: The rate at which research changes in the health sector is overwhelming – sometimes [new insights come out] at a monthly rate. How does a clinician stay current, manage and analyze the information in a way that is useful to patient care? This is where computers provide value. There are many ways to remove complexity from the way that you view data points today. For example, with Excel, you can take a grid of data points and turn it into a graph with relevant ranges or color, developing an easy way to see what is going on at a moment's notice. A graph of a patient's cholesterol or hypertension readings over time can tell you more about what is going on than a stagnant piece of data from an individual blood test. Software here can reduce information density across the board, making it easier to manage and digest the important data.

Observational research shows that more than 25 to 30 percent of physician or nurse time is spent searching for data in fragmented systems in the hospital setting. Software can reduce hunt time and deliver a meaningful image about a patient. Not only does this dramatically change productivity levels, but it also helps make decision-making more consistent and more reliable.

Pulse: How do you see information pushing innovation in science in the future?

PN: Information plays a huge part in research, driving more innovation in science and accelerating discovery. We are focused on trying to connect genomics and proteomics research with clinical activity in hospitals. We recently partnered with Scripps Translational Science Institute, Navigenics, and Affymetrix to launch a first-of-its-kind research study that will assess the behavioral impact of personal genetic testing on people who choose to receive such screenings to identify their potential risk for developing certain diseases.

Microsoft is also focused on basic clinical trial research in computational biology. We are asking, "Can our enterprise tools allow discovery to happen when we combine large data sets?" We are building tools and a knowledge base to develop strategies for a common infrastructure so research can spend less time manipulating data and more time learning

Continued on PAGE 38 >

Marina Tarasova
WG'10

The Pulse: The formation of valuable partnerships is clearly a growth strategy for Google Health. Notable recent partnerships include The Cleveland Clinic, HIMSS, the MyCareTeam, and MyDailyApple. Can you discuss how Google plans to capitalize on these alliances over the next 12 to 24 months?

Jerry Lin: The partnerships that Google Health forms generally fall into one of two buckets. The first bucket is data providers. Data providers basically allow users to be able to import a copy of their primary health information into Google Health. The second bucket [involves] taking advantage of that information by sharing it with third-party applications that can help patients act on their health information.

So, Cleveland Clinic falls in the first bucket. If you are a patient [at a Cleveland Clinic facility] you can ask the hospital to send you a copy of the details that they have on you through Google Health. An example of the second type of partner is The American Heart Association, which provides a heart attack risk calculator. Based on certain pieces of information (for example, what your blood pressure is or what your cholesterol levels are), it can provide you information on what your risk of heart attack may be in the next decade and what you can do to change it.

The partnerships in both of these categories are really important because you have to have the data in order to power the applications and you also must have the applications in order to help the patient make sense of the data. They have to go hand in hand.

In particular, there have been a few Google partnerships that have launched very recently which we are really excited about. One of which is Blue Cross Blue Shield of Massachusetts, which is the first payer. Anyone who is a member of Blue Cross Blue Shield of Massachusetts can import a copy of her health data into Google Health. Additional partners that have also just launched include Drug Fair and Meijer as well as CVS Caremark.

Pulse: My next question deals with patient privacy. Despite the wide acceptance of online banking and credit card transactions, people are still incredibly wary of allowing their health information to be stored online. How can EMR [Electronic Medical Record] providers convince patients that their privacy will be maintained?

JL: I think that the biggest factor is showing the utility of a service. If people can see the value of having different medical data stored in one central location online and they feel that bringing this data online is useful to them, then I think they will get past any fears or myths around online privacy concerns. I think it will come down more and more to the benefit side of the equation. So I think what is going to be most convincing for patients will be for them to really understand what benefits they can capture from having their medical records stored online.

Pulse: What is the largest hurdle that you think is facing Google Health adoption today?

JL: The hurdles that we are facing are something of a chicken and egg problem. That is, users need to have data in order to take advantage of a lot of the third-party applications that build on top of the Google Health platform and help users manage their health better. So, if you go online today, if you have a Walgreen's account or you are a patient of Beth Israel Medical Center in Boston or the Cleveland Clinic in Ohio, you could download a copy of your medical records to Google Health.

But what if you aren't a member at one of the institutions that are integrated with Google Health? That's a barrier because people aren't going to be that excited about typing in ten to twenty years of medical history by hand. However, being able to automatically download your medical data from integrated organizations is the tremendous value Google Health offers its users. But it also takes time to build these partnerships and create scale, or what we refer to as the "network effect."

Pulse: I would like to ask about another type of partnerships having to do with integration with

JERRY LIN
PRODUCT MANAGER, GOOGLE HEALTH

Mr. Lin is a Product Manager for Google Health and helped launch the product to the market. Mr. Lin works on areas on the health team that are related to data interoperability and privacy. Prior to joining Google, Jerry interned at Athenahealth, where he identified a revenue opportunity by helping doctors engage in Pay-for-Performance programs. Jerry has also worked in product development at RosettaMed, a startup focused on streamlining patient data collection. In addition to holding an M.B.A. in Health Care Management from The Wharton School of Business at the University of Pennsylvania, Jerry holds an M.S. in Electrical Engineering from Stanford University.

medical device and diagnostics technologies. What is the potential for Google Health to integrate and automate with these newly emerging technologies (or existing technologies)?

JL: We think that Google Health has a lot of potential in terms of helping users to track all their health information. Nowadays, more and more data is being generated by personal health monitoring devices, for example blood pressure meters or glucose meters. So, we do want to make it easy for users to keep track of that information and upload it to their PHR [Patient Health Record], and we are currently working with some device organizations to make that happen.

In terms of standards for devices, Google recently joined the Continua Health Alliance. Google is particularly interested in supporting Continua because they have a broad array of industry members who are devoted to promoting standards that are published and managed by the industry as a whole versus having device manufacturers conform to any one specific proprietary standard for interoperability.

Pulse: Could you discuss how Google is addressing both the baby-boomers and their children and family's health care record management needs? Are there currently ways to help the elderly or their families better integrate their health data?

JL: A very large percentage of people who are 65 and older take five or more medications regularly. Getting prescriptions through integrated retail pharmacies and PBMs [Pharmacy Benefit Managers] can help to make it easier for users to capture their medication history in Google Health. Once that data is in Google Health, several third-party services can help users be even more effective in managing their medications. For example, there is a third-party service called e-Pillbox, which can read a list of a user's medications and can send reminders when the person should be taking a specific medication. There is another service called PatientAssistance that can help users find different places where their medications are being sold We can integrate third-party systems that can help people price shop for their medications. These services offer a convenience factor. So we now can have a number of offerings within the medications space that we hope will be useful for this segment.

Pulse: Moving on to another area where IT and vendors such as Google Health could help the medical community: aggregation of data for clinical trial and patient selection purposes. In what ways do you see Google Health working towards achieving this goal?

JL: I think that Google Health works a lot on the data aggregation front by helping users get their information in one place. In terms of specific applications around trials, that is an area where we are very happy with other people coming in and providing functionality. So, for example, today if you start a Google Health Account, you can sign up for a third party application, called TrialX. With the user's permission and voluntary election, the service can read the user's Google Health profile to find relevant clinical trials that might be going on in his area. This is an example of an innovative service that is coming out of the new third party ecosystem.

Pulse: If physicians are looking to do a query of a certain patient demographic - for example, all of their diabetic patients - in order to send them an alert about a new medication, most of them must dig through their filing cabinets of charts to find this information. This is often inefficient and may not provide them with the results they want. Do you ever see Google Health providing an overlay of patient records (anonymously where needed) that could help physicians accomplish such goals?

JL: Collecting a lot of data and learning from that data is very interesting. That said, Google Health has made a promise to its users to respect their privacy, so I cannot foresee Google Health offering records–even de-identified records–out for query usage for example. But I could see third-party services saying: "Hey, you should donate your medical profile anonymously to this application and we will help researchers do hypothesis testing." In that case, it would be a user's choice. They can choose to participate in that type of application or that type of program if they want to.

Pulse: You've alluded to the importance of standards several times in our conversation. Do you think that the government could help facilitate this in any way or do you think this has to come from industry?

JL: I think that the government has a good start in this area with its work on harmonizing standards through the Healthcare and Information Technology Standards Panel (HITSP) and initially funding CCHIT (Certification Commission for Health care Information Technology). Standards will continue to require additional work, and the government could help foster those efforts.

The CCHIT is certifying Electronic Medical Record (EMR) systems based on the Healthcare and Information Technology Standards Panel's work. They also just started developing criteria for Personal Health Record (PHR) certification of which Google has been involved with. The idea behind CCHIT is that in order for an EMR/PHR system to get certified, they need to fulfill a minimum set of requirements. This is like a Good Housekeeping seal of approval for health care. This would not deem that a system is the best, but rather that a system will meet certain standards.

Another important area that relates to better interoperability is the coding of medical terms. So, for example, having a national language for organizations to refer to specific medications by specific codes would be important or having widely adopted code sets for procedures would be very helpful in promoting interoperability.

Emily Cooper
WG'10

The Pulse: What do you see as the greatest areas of progress and the greatest points of stagnation in the current health IT market space?

Jeff Goldsmith: There has been a steady increase in the investment by hospitals and physicians in health IT in the last five years, at a rate of about 10 percent per year. However, there are still huge gaps in coverage. Most hospitals and hospital systems have some degree of automation of their clinical process, but only about 15 percent have gotten all the way through to computerized physician order entry. So, one could argue that the progress has been very slow despite steady spending. On the physician side, only 15 to 20 percent of physicians have actually computerized their records despite the fact that there are a lot of competitors in the [electronic medical record] space, with a lot of product offerings. So, in summary, a lot of spending – very slow progress.

Pulse: What do you see as the drivers behind the slow progress? Is the lack of adoption largely due to misaligned incentives?

JG: There are definitely misaligned incentives. In most other industries, the implementation of automated solutions results in lowered operating costs, and that hasn't been the case in medicine. If there is an efficiency or productivity gain, it hasn't be identified. So that raises a lot of questions about whether the tools are really powerful enough or robust enough to

"In most other industries…automated solutions ...lowered operating costs, and that hasn't been the case in medicine."

have made a difference in operating performance, and I would argue that they haven't.

If you automate medical records and ordering and the nurse still ends up only spending 30 to 40 percent of her time actually nursing, then you don't gain anything. From a macro point of view, if [the hospital] lays off coders and billing clerks, but then has to hire a bunch of $100,000 per year database managers to keep the system up and running, then that isn't a big win, and that has often been the case. Electronic Medical Record (EMR) systems are so complex, fragile, and difficult to maintain and use, and so expensive to install that they have not produced quantifiable, meaningful operating savings.

There may be, and here the evidence is equivocal, improvements in performance and safety, but even there, there is a powerful intuitive argument that the gain stems from the ability to read typed orders over handwritten ones, and not from improved communication. Just because the system is in place, do the physicians read the nursing notes? Do the nurses read the physician's notes? Does the pharmacist read the physician's notes and see all of the other live orders for a patient? In some cases yes, in some no. People are not using [electronic medical interfaces] as groupware. Medical record technology has not broken down the silos to the extent that many of us expected.

Pulse: Is this lack of measurable improvement a function of ineffective software, the users, or a combination of both?

JG: Robert Wachter put out an excellent article on his blog asking: "Why can't an electronic medical record be more like Facebook?" What he is basically saying is that now we have fancy electronic silos instead of each department with its own paper records. He discusses a situation where residents built an IT tool to summarize patient situations for transitioning care at shift changes. The nurses then asked for access, implying that the electronic system put in place by the hospital system wasn't functional. I don't know how long it will take to implement a system that integrates across functions.

Pulse: Some view the government as the only player with enough power to implement a standard electronic medical record across providers. Is there a way for the Obama administration to use the 10 billion dollars per year allocated to health IT to implement a national medical record, leveraging the government's control over reimbursement to facilitate adoption?

JG: For the last four years [the government] has been trying to promote interoperability by convergence on standards for clinical information systems. That, too, has gone very slowly. Unless you provide a powerful carrot in the form of money to implement these systems, you won't see convergence.

What the vendors want is a walled garden. Interoperability would require vendors making different applications talk to one another, and that's not in the economic interest of the vendors; each vendor wants exclusive contracts. Implementation faces a strong economic current, and the way vendors market is sort of like "join our tribe, and we'll solve all your problems."

I'm not sure the government has enough power to compete. It has taken 12 years to get the data

"The privacy issue is not going away because… this information is more intimate than what is in my checking account."

standards that we currently have around HIPPA, including a claims attachment and provider ID. There is still no patient ID because the privacy lobby stopped it. You could make an argument that focusing on data standards was the wrong place to start.

Pulse: What approach would have been more effective?

JG: I honestly think that the whole idea of creating a personal health record and personal data networks is very 1970s. What's needed is that whenever a person goes somewhere, they have their record with them, and it gets updated. You can store most of what you need to know about a patient on a 3GB thumb drive. Five or ten years down the road you will actually be able to write it on a patient using a memory spot. A memory spot is the next stage in the evolution of data storage beyond RFID. It can hold as much as 5GB, a layer of encryption, and operating instructions, and is about the size of a capital "O" in a line of type. People could just always have it on them, like in an earring for example. This avoids the problem of Google or Microsoft trying to hold all of the data, and potentially commercializing it with advertisements and emails.

Pulse: Do you have a theory as to why the Veteran's Affairs (VA) EMR system hasn't been more widely adopted?

JG: My commercial friends tell me that despite it being an old system, it is still more functional than any of their products, but the problem is how do you fit that system into all the different hospital settings and who maintains it? That's the expensive part. It is so essential to massively customize everything, that by the time you've done it, it bears no relationship to the very same system implemented in another hospital. Taking the VA system and plunking it down into the Hospital of the University of Pennsylvania isn't going to work. Who's going to do it? The VA system is written in MUMPS, which is like cuneiform or Sanskrit. It is an obsolete computer language designed before modern database management. To be useful, the system will have to be rewritten in another language, which is probably not the answer.

Pulse: Despite the wide acceptance of online banking and credit card transactions, people are still very wary about allowing their health information to be stored online. How can EMR providers convince patients that their privacy will be maintained?

JG: That's an interesting question. I don't really know. I think the problem is that if you create a record that is digitally actionable, then there is the fear that the employer or the payer can use the information to deny you benefits. That's the privacy concern. Unless there is a very credible wall between the payment system and the delivery system, those issues of trust are going to stay.

That's my reason for thinking that, at least with the PHR, if I actually have physical possession of it, it's not like it's out there in the ether and someone can just pry into it and know all they need to know about me. I don't think the privacy issue is going away because people have actually been harmed by the disclosure of their medical information. This information is much

JEFF GOLDSMITH
PRESIDENT, HEALTH FUTURES INC.

Jeff Goldsmith is President of Health Futures Inc. and an internationally known health care change speaker. Jeff's specialty is health care trend analysis, a process by which he tracks technological developments, determines what they mean to the health care industry and then develops appropriate strategies for implementing the new technologies into current health care business and practice models. Known nationally as a leading Futurist, Jeff is actively involved in the health care industry and has served as National Advisor for Healthcare to Ernst & Young for 12 years, and lectured for 11 years at the Graduate School of Business at the University of Chicago.

more intimate than what is in my checking account. Google mines my search history; they can look at where I go on the internet if I go through Google. Well, suppose that all of your health information were in there. Maybe I'm being a Luddite here, but I don't think those issues are technical issues of security, I really don't. The security is not the problem. The problem is what actual legal rights the patient has in regards to the employer's access to their information, and the payer's access to their information, and for what purposes [employers and payers] look at it.

Pulse: Beyond EMRs and PHRs, do you see any information technology changing the landscape of health care within the next two to five years?

JG: I think we are in kind of a flat spot here. I don't see a breakthrough technology that is going to change the clinical information side of health care IT anytime soon, although I could be wrong.

We've been waiting a decade for voice recognition so you can just talk to the record. To me, the central problem is that we have become obsessed with documentation. What we have not exploited is how we use IT to improve communication inside the clinical team, or between the clinical team and the patient. That was the plaintive cry from the Wachter post. This really needs to be more of a communication tool and less of a documentation tool.

There is an interesting company called Myca that has built a technology that is essentially a communication platform between primary care physicians and patients, who they refer to as "members" since they are not necessarily sick, that works exactly like Facebook. In other words it's a social networking interface, and it enables you to become a member of a physician practice and to talk to the physician through the medium that you choose. There is an EHR/PHR embedded in the software but it's not a record system, it's a communication system. I think that tools like that are where this field needs to go. One of the questions that I asked with an office-based EMR is "Can you launch or manage communication with patients?" The answer is "No" with most of them. That is a grievous shortfall. [Editorial Note: Mr. Goldsmith currently works with Myca]

Pulse: If you could implement three innovations in the IT space what would they be?

JG: I think we need to eliminate fax and paper from adjudication and the medical claims process. I think that would actually be bigger than implementing the electronic health record. I also think we need a secure solution to the patient ID, or we will never have the ability to move the data around. Perhaps we could use the public key, private key encryption model. Finally I think these tools need to get significantly better on the presentation end. They have to become effortless to use and we have to figure out a way to use modern visualization tools to enable people to dive into the information about patients, get it when they need it, and not get stuck in these Windows 95 type nesting things with screens inside of screens, inside of screens.

STATE OF CONFUSION: SURVEYING THE PUBLIC ON HEALTH CARE'S "BIG IDEAS"

In this article, we use a basic survey to explore patient attitudes towards some of the most vexing debates in the health care industry. The results highlight notable disconnects between the industry and average citizens, providing food for thought about how perceptions may affect politics, policy and reimbursement in the upcoming years.

Allison Walsh
WG '10

The desire to 'fix' the health care system has been a theme in American politics since the late 1980s, perennially listed among the top six issues in presidential elections[1]. What has changed over the years (and depending upon one's political persuasion) is the villain of the day. Are spiraling costs due to a lack of personal responsibility and an unhealthy lifestyle, the price of drugs, or perhaps over-utilization of clinical technologies? For every problem there are multiple, often contradictory, "solutions" being offered. Over the past three decades, market solutions such as HMOs and government solutions such as national health plans or health savings accounts have divided and confused America, inciting significant public and industry backlash.

The American public clearly realizes that their health care system is in need of reform. In a recent Gallup poll, 14% of Americans declare that the health care system is "in a state of crisis" and 59% think the health care system has "major problems.[2]" In light of this confusion and frustration, we at The Pulse decided to reach out to average Americans (and yourselves, the survey is online at: http://www.whcbc.org/pulse.asp) on a variety of recently proposed solutions. This survey is far from definitive. It was intended to entertain as much as to inform, but it turned out to be quite revealing, highlighting fracture-points in how people understand key questions of policy and profit in the industry.[3]

We dove into three "hot button" areas: (i) market-oriented solutions to controlling health care costs through HSAs/High-Deductible Health Plans; (ii) pharmaceutical costs, utilization and the validity of pricing; (iii) the appeal of various aspects of state intervention in health care, including the tradeoffs that patients would face in a different system.

Will Cost-Sharing Promote Enlightened Self Interest?

The argument: Patient engagement and price transparency will lower health care costs.

High-Deductible Health Plans (HDHPs) feature high deductibles and relatively low premiums – making them appealing to employers. By making the first $1,000 (or more) of health care expenses each year an out of pocket expense for patients, proponents theorize that patient consumption of health care "products" will become more rational and lead to cost savings for the system as a whole. Proponents also believe that patients, faced with more direct feedback on the consequences of their lifestyle choices, might become more engaged in caring for themselves, leading to further long term cost savings.

What we asked: HDHPs currently cover only

Figure 1: High Deductible Health Plans

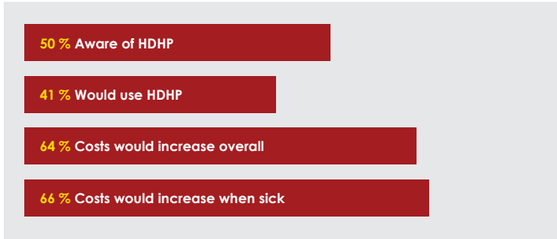
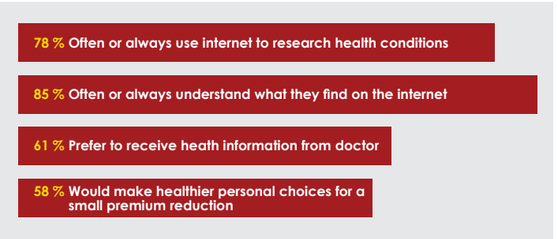


Figure 2: Consumer Behavior



about 3% of the insured American population. Will Americans ever adopt it en masse? We asked a few basic questions about high-deductible health plans, attempting to ascertain how well the public understood them and whether individuals felt that HDHP approaches would save them money.

What we heard:
- Awareness of HDHP remains limited (50%) and interest in using these plans is relatively low (41%), largely due to a perception that patients using them would face higher costs. (See Figure 1)
- Patients are engaging more actively in their own care and are saying that they are willing to change behavior for a fairly minor reward or premium reduction. (See Figure 2)

Can We Continue to Fund Innovation?

The argument: Cutting spending on clinical technology and pharmaceuticals is key to reducing health costs.

The pharmaceutical industry has been a political target for years and some health economists argue that medical technology drives costs rather than cuts them.

What we asked: We thought it would be interesting to see if co-payments affect consumer perceptions of drug costs, and how much survey respondents think it costs to bring a drug to market.

What we heard:
- The majority of respondents pay a co-pay for drugs and do indeed think they are too expensive, but only 22% indicate that they have stopped taking a medication due to cost. (See Figure 3)
- The majority (60%) of respondents thought that a drug costs less than $100 million to develop, indicating a major communications gap for the industry.

Should Government Be the Insurer of Last Resort?

The argument: The only way to address the issue of access to health care is to create government-provided health insurance to cover the uninsured and provide a safety net for those who can not access employer-based insurance.

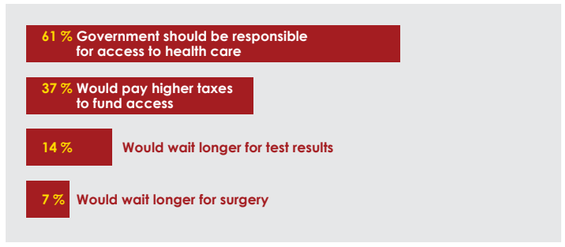
President Obama's electoral victory has brought this issue back to center stage and has already provoked a strong reaction amongst industry insiders and average Americans alike. Obama's plan aims to increase the number of people who have health insurance by spending approximately fifty to sixty-five billion dollars annually to provide investments in areas ranging from information technology to having government act as a backstop insurer[4]. All told, Obama believes his plan can be paid for by reversing the Bush tax cuts and that it will save the American family $2,500 per year.

What we asked: We asked respondents about their attitudes to government intervention in principle, and also how they would respond to some of the common issues with a more centralized health care system. Our goal was to see how clearly respondents perceived the tradeoffs that often accompany systems with more government intervention.

What we heard:
- There is strong support for government intervention

Figure 3: Drug Costs and Behavior

Figure 4: Government Involvement in Health Care



to increase access.
- There is less willingness to pay additional taxes to add to coverage.
- There is almost no willingness to accept slower tests or less access to services than is currently received.
- The "average American" would prefer to have his cake and eat it too… thank you very much! (See Figure 4)

CONSUMER-DRIVEN HEALTH PLANS

Insurers like Humana continue to forge ahead with tools aimed at making Consumer-Driven Health Plans (CDHPs) work as they were intended to. One such program offered by Humana in conjunction with Virgin (the Virgin Health Miles Pedometer Program) rewards members by taking steps with points redeemable for gift cards. While traditional wellness programs see response rates around 10%, the Virgin program has yielded 35-40% engagement across approximately 150,000 members. David Bartley, an innovation manager with Humana, credits this success to the immediate and tangible nature of the feedback members are receiving. As wellness initiatives align incentives more appropriately, and deductibles are set more appropriately to offset the moral hazard that kicks in once deductibles are met, CDHP users may improve their usage to the benefit of insurers, employers, and even themselves.

What Does It All Mean?

Attempts to communicate the future of health care and the impacts of proposed solutions are not working. While our respondents felt that health care reform was an urgent issue, they appeared woefully under informed about both their options and the implications of these choices for their care and their pocketbooks.

If insurers hope to preserve an opportunity for a market based solution they must act quickly to teach the public about the costs of care and the benefits of cost-sharing to sustain the existing health care delivery system. If government insurance is the way of the future, leaders should provide a better explanation of the real costs and the associated tradeoffs patients will face.

If the pharmaceutical (and likely device and biotech) industry hopes to preserve the U.S. as a lucrative market for their products, new efforts are needed to teach the public about the costs and benefits of leading global innovation.

Assuming the economic experts are correct, something must be done to control health care costs in this country, and soon. No matter the solution selected, tradeoffs will be required of both industry and consumers. You, The Pulse reader, are in a unique position to lead the industry towards a more effective relationship between suppliers and consumers, and to share your knowledge with the rest of America to create a better health care system.

FOOTNOTES:
[1] Blendon, Robert J.; Altman, Drew E.; Benson, John M.; Brodie, Mollyann; Buhr, Tami; Deane, Claudia; Buscho, Sasha. "Voters and Health Reform in the 2008 Presidential Election" NEJM 359;19 11/06/08.
[2] http://www.gallup.com/poll/112813/Americans-Rate-National-Personal-Health care-Differently.aspx
[3] Methodology: Twenty-seven individuals over the age of 21 responded to this survey which was distributed on the University of Pennsylvania campus and at a set of medical facilities in St. Louis, MO
[4] Information technology, prevention and management of chronic conditions, increasing insurance industry competition, reducing underwriting costs, and providing reinsurance for catastrophic coverage, from http://www.thehealth careblog.com/the_health_care_blog/2008/03/a-detailed-anal.html

WANTED: NEW MOLECULES— HOW LARGE PHARMA SOURCES INNOVATION

Is the pharmaceutical industry as we know it dying? The patent cliff of 2011-2012 will result in the largest branded drug manufacturers losing about 25% of revenues. Patent expirations are, of course, nothing new for pharma and many major products have come and gone during its history. Despite huge losses in the past, the industry has been able to sustain itself and even grow through the discovery and development of new products. The problem today is a dry pipeline, with productivity levels well below those of previous years.

The U.S. Food & Drug Administration approval of NCE's (new chemical entities) was at an all-time low of 19 in 2007. When imaging agents, metabolites and pro-drugs are excluded, this means that the industry provided 14 novel products in a year when 15 products lost patent protection - in other words, it was net negative in terms of patented innovation. That this decline occurred despite massive investment in R&D, which rose from 8.9 percent of sales in 1984 to 16.2 percent of sales in 2000, has been the cause of consternation across the industry.

GlaxoSmithKline provides an interesting example of how one company is grappling with this problem. The firm has experimented with a novel, smaller-team R&D structure and has refilled a pipeline that was nearly empty at the time of merger. GSK is currently pushing further into lab-based funding, inviting outsiders to vet scientific ideas and continuing to carefully prioritize disease areas to target. The Pulse interviewed Dr. Yvonne Greenstreet, Senior Vice President and Chief of Strategy, Research and Development at GSK, to dig deeper into how GSK's approach to pharmaceutical innovation will need to change given current market conditions and the new GSK strategy.

Richard Whelton
WG'10

The Pulse: Several large pharmaceutical companies are currently rethinking their internal research departments. One example is the decision by Pfizer to exit cardiovascular research. GSK's current research model, Centers of Excellence for Drug Discovery (CEDD), organizes the business by key disease areas. How will GSK's research focus and model change going forward?

Yvonne Greenstreet: The CEDD model has been a real success and we feel it has delivered progress for the organization. When it was created at the time of the merger, our pipeline was pretty much empty. After five or six years, it became one of the healthier-looking early-stage pipelines in the industry. We now have around 130 projects in the pipeline.

In terms of areas to investigate going forward, we recently concluded an 18-month-long intensive study to evaluate a range of different diseases from the perspective of unmet medical need that are ripe with discovery opportunity. We selected eight key therapeutic areas to focus on: immuno-inflammation, neuroscience, metabolic pathways, oncology, respiratory, infectious disease, ophthalmology and biopharmaceuticals.

We also examined the CEDD model and said, "Okay, how can we make it even better?" That led to the thinking around what are called Discovery Performance Units (DPUs), in which small, lab-sized entities sat within a CEDD. Each one focuses on a particular pathway or a particular mechanism and is driving the discovery of medicines in that area.

The small entrepreneurial grouping of the DPUs is important because discovery usually takes place in small teams, not necessarily in 15,000-person organizations. Therefore, we're trying to construct small, entrepreneurial groups that are headed up by a strong leader with expertise in a particular area. What's really important about the model is that we are setting up a three-year funding mechanism. So, rather than these groups having to come on an annual basis and ask for budgets, they are given a three-year runway, which is a little bit more akin to the situation that a biotech company might find itself in.

"[R&D teams] are given a three-year runway, a little bit [like] the situation a biotech company might find itself in."

The plans that these groups develop are reviewed by a group called the Discovery Investment Board. The unique feature of this decision-making committee is that it's not just composed of people from within GSK. We have venture capitalists and biotech CEOs at the table who provide an external objective perspective on what's being proposed by an individual DPU. The Board will also provide a perspective on what they think about the quality of the management team, as well as the business plan and the delivery. This process injects greater rigor into the decision-making process, as well as the slightly longer funding runway. Overall, we'll provide a more entrepreneurial environment for the scientists to operate in.

"We have set a target of 20% of the pipeline to be coming from biopharmaceuticals by 2015."

Pulse: Do you feel this environment will help attract scientists? Won't scientists be put off by the potential for their funding to be cut after just three years?

YG: In terms of attracting scientists, we have already seen a positive impact. We've been able to attract senior folks from academia to biotech. For example, one of the co-founders of Domantis [a wholly owned subsidiary of GSK as of January 2007] has stayed on to head up the biopharma unit. Normally, when you buy companies, the senior management leave when they get their checks. We've also hired a very impressive academic for our R&D unit in China, and great scientists to head up our inflammatory business. So yes, the prospect of coming into a large pharmaceutical company, but being able to run essentially a lab-sized unit with a degree of empowerment and accountability, is attractive.

In part, though, we'll have to wait and see what happens in three years' time. Maybe some groups will have so much opportunity we'll want to significantly increase the investment and some will have less opportunity and we'll want to decrease the investment. But the critical thing is that we've set these teams off in a direction to allow them to fully explore the opportunities that they feel they have, and they're absolutely held accountable for deliveries. They declare what they're going to produce in their plan, and they'll be judged on that.

Pulse: The blockbuster model is looking increasingly difficult to sustain, and clearly does not fit with GSK's strategic emphasis on reducing risk for investors. What will happen to the blockbuster model at GSK? How will GSK deliver more "products of value"?

YG: Although we consider ourselves a relatively diversified company, GSK still has around 60 percent of sales coming from just 10 products. A key aspect of our strategy going forward is about recognizing that it's incredibly difficult to deliver a blockbuster to order. So we are moving to a model that's much less blockbuster-dependent, and much more based on a larger range of potentially smaller opportunities. Clearly it's great if you can get blockbusters, but we believe that it's going to be a much more sustainable business if we're able to develop an approach that allows us to develop a range of products on a regular basis.

Many of these may end up being smaller than blockbusters because we're going to have to come up with a few products every year rather than one product every three years. We have recognized that trends are moving the industry towards smaller populations for particular medicines. The regulators are certainly much more comfortable with medicines that have clear safety and efficacy in a particular population, and I think the payers are not overly enthusiastic about paying for medicines for large swathes of the population, especially if these medicines only have small incremental benefits. So I think that all of these factors lead one to believe that on average, [the projected market for] each new chemical entity is probably going to be a size smaller going forward than it was historically.

Pulse: In a bid to boost faltering pipelines, pharmaceutical companies are increasingly looking to source projects externally. GSK appears to be following a similar path, having recently stated that it expects up to 50 percent of its drug discovery could be sourced from outside the company in future years.

YVONNE GREENSTREET
SENIOR VICE PRESIDENT, CHIEF OF STRATEGY, R&D, GLAXOSMITHKLINE

Dr. Yvonne Greenstreet has over 16 years of global experience in the pharmaceutical industry. She is currently Senior Vice President, Chief of Strategy, R&D for GlaxoSmithKline, a $37 billion leading research based pharmaceutical company operating in 37 countries selling medicines across a variety of therapeutic areas. Prior to this position, Dr. Greenstreet was Senior Vice President in Medicine Development where she defined pipeline strategy and brought new medicines to market. Under her leadership, her global team built a promising pipeline of innovative medicines for treating a wide range of conditions including inflammatory, gastro-intestinal, musculoskeletal and urogenital diseases. Previously, Dr. Greenstreet served as Vice President and Head of European Clinical Development and Medical Affairs, and as Chief Medical Officer of GSK in Europe. Dr. Greenstreet graduated in medicine from the University of Leeds, and studied at several London teaching hospitals including St. Thomas', St. Mary's University College and St. Bartholomew's. She obtained an M.B.A. from INSEAD, France.

How does GSK plan to source such a large proportion of its technology?

YG: There are a number of ways that we are doing this. As well as straight licensing, we have done a fairly significant number of option-based deals, and this gives us a real opportunity to get engaged with assets and technologies that we find exciting, but allows us to manage the risks around our investment.
We're also looking at academic collaborations. For example, we have got some interesting collaborations with the Harvard Stem Cell Institute to allow us to understand developments in stem cells.

We are also continuing to look at the acquisition of companies that we think have exciting assets and/or technology platforms. The recent acquisition of Domantis fits into that category. We felt that we were buying into an exciting new technology platform [domain antibodies], which had key advantages. For example, the fragments of antibodies that are addressed are much smaller than monoclonal antibodies and are therefore easier to manufacture. The smaller size means that you can also consider different delivery mechanisms, topical or inhaled. So we thought it was a significant platform opportunity that really allowed us to move forward and build a significant business for GSK in biopharma. We have put a lot of focus on building a biopharma business because the economics are different and we think there's still scientific opportunity to go after. We have set ourselves a target of 20 percent of the pipeline to be coming from biopharmaceuticals by 2015.

Pulse: The marketplace for accessing pipeline products from smaller companies, however, looks set to becoming increasingly competitive. How will GSK stay ahead of the competition?

YG: Recently, The Boston Consulting Group did some analysis on how large pharma companies are viewed by biotech, and GSK did incredibly well in terms of what we're able to offer partners. This goes right through from creative deal structuring, to allowing partners to develop the companies in the way that suits them, to making sure that we got senior people at the table at the right time, to just being great people to work with.

Part of our ability to compete is also going to come from just doing the business development job as well as we can so that biotechs look to us as a company that they would want to work with. Take Sirtris, for example. We bought Sirtris, but we've actually kept it as pretty much a standalone unit up in Boston because we liked what they're doing and want them to continue doing it. We want to make sure we get value out of their pipeline, but we don't feel a need to put in new management and change the way they're doing things. I think that's attractive to a number of biotech companies.

Pulse: Emerging economies, such as the BRIC nations, have rapidly growing pharmaceutical markets and stronger scientific resources. How is GSK looking at pharmaceutical innovation with these markets in mind?

Continued on PAGE 38 >

REACHING THE TARGET: THE SECRETS OF RUNNING A SUCCESSFUL CAMPAIGN

The launch of the HPV vaccine, Gardasil, was a revolutionary change in what had been a quiet industry. Historically, pediatric vaccines were most of the market and demand was driven by pediatricians and school mandates. With few adolescent and adult vaccines previously developed, there lacked a proven method of selling a preventative medication for an unfamiliar disease to a potentially apathetic consumer base. Yet, as Beverly Lybrand, General Manager of Vaccines at Merck, describes to The Pulse, there is indeed a way if one is willing and able to create an unconventional campaign.

Marina Tarasova
WG'10

The Pulse: What are the most pressing issues and challenges on your plate today with respect to the vaccine business at Merck?

Beverly Lybrand: A key aspect of the vaccine business at Merck has to do with the pace of change. Merck has a long history of participating in the discovery and introduction of vaccines, but over the past handful of years, we have been able to bring four new and exciting products to market. So, with that there came a number of fundamental changes in the vaccine business. We make many of the foundational pediatric vaccines that most children receive and we announced two new vaccines to that market. Following that, we created a completely new paradigm in vaccine discovery and marketing with the introduction of Gardasil and Zostavax because they are for age groups that are not as regularly vaccinated and they both target very different disease states for prevention. So, change is the theme and with this introduction and evolution of the new vaccines and new vaccine markets, managing and keeping up with the pace of change has been one challenge that pretty much everybody in the business deals with on a day-to-day basis.

Pulse: I am glad that you brought up the pace of change because catalyzing change in health care is the theme of the conference this year. I would like to follow up on the successful launch of Gardasil. Could you tell us what have been the most exciting and challenging aspects of running this launch?

BL: The launch of Gardasil has been remarkable. The vaccine came about from the initial discovery of a link between a virus, the HPV virus, and cancer, cervical cancer. So in itself it is really a stunning finding which was recognized when Professor Harald zur Hausen, who discovered that connection, was recently awarded the Nobel Prize. Having a vaccine that can help prevent cancer is one of the most profound aspects of Gardasil. Cervical cancer is such a significant global medical problem – it is estimated that two out of six women are diagnosed and eventually die from cervical cancer around the world, which is just stunning. But beyond that, from a business perspective, the notion of working across a complex set of audiences and stakeholders who need information about the diseases caused by HPV was, and continues to be, challenging. Stakeholders include those who would be vaccinators, policy makers, and recommenders of vaccine policy. There is such a broad array of interested parties in the availability of Gardasil and this broad applicability is a hallmark of the product and its launch. A good example of this can be seen in the relevant physician specialties. We educate across various specialties including pediatricians, primary care physicians and then on through obstetrics and gynecologic specialties. So, even among the physician specialties, there is a differing set of needs and information that we have to plan for. Merck had to work cross functionally, which has been our strength, but this breadth really became a hallmark for the Gardasil launch. Because Gardasil and Zostavax serve the adult and adolescent markets – which were previously not fully developed -- I would venture to say that everything that is being done for marketing these products is novel.

"…our programs are designed specifically to recognize the underlying information-seeking behaviors of our audiences. "

Pulse: I noticed some of the nontraditional marketing

BEVERLY LYBRAND
SR. VICE PRESIDENT AND GENERAL MANAGER ADOLESCENT & ADULT VACCINES, MERCK & CO.

As Sr. Vice President and General Manager Adolescent & Adult Vaccines, Beverly J. Lybrand directs the global commercialization strategies and operations for Gardasil®, the vaccine for cervical cancer and HPV diseases, Zostavax® for shingles and PHN, Pneumovax®, and Hepatitis A and B products. She leads the Global Franchise Operating Committee directing global franchise efforts for the franchise, including all clinical, regulatory, policy, and commercial activities and also serves as a member of the Global Vaccine and Infectious Disease Leadership Team. Formerly, Ms. Lybrand was Vice President, U.S. Human Health Marketing, Respiratory Franchise Business Group, Merck & Co., Inc., and directed all U.S. commercialization efforts for the Respiratory Franchise including Singulair® for asthma and Allergic Rhinitis, as well as new products and licensing candidates for Respiratory diseases. Prior to joining Merck, Ms. Lybrand was a consultant for health care clients at APM in New York City. Ms. Lybrand received a B.S. degree in nursing from Trenton State College and her M.B.A. from the Wharton School, University of Pennsylvania.

tactics that were used for the launch of Gardasil. I remember watching the "One-Less" ad during the premier weekend of the *Sex and the City* movie. I saw some of the Gardasil materials on postcard stands. Could you comment on other nontraditional marketing tactics that were used and what, if anything, would you do differently?

BL: What you are noticing is that our programs are designed specifically to recognize the underlying information-seeking behaviors of our audiences. The fundamental thinking behind the launch of Gardasil was to understand the customer- whether they are moms or parents of young girls, or young adult females themselves. You will see this, for example, in a lot of our web-based strategies, if you have a chance to go on to gardasil.com. We have shared consumer information through a Q&A format for parents, a place for moms to check in and receive information so that they can prepare to talk to a doctor.

What we found when we talked to moms and young adult females is that when they receive information that there could be a virus that would cause the cancer, most were really surprised. We then knew that before we began to talk about Gardasil, we needed to provide disease state information to the public. So, for the consumers, we created and launched the "Tell Someone" campaign before Gardasil was approved, which highlighted some of the disease state facts. This campaign was supported with website resources such as video vignette stories of young women that capitalize and acknowledge the power of peer-to-peer communication. Recognizing the pervasive nature of social networking, we also created a Facebook group around HPV information. Following the launch of the campaign, this information is starting to become part of the general awareness.

Pulse: Merck has been successful in increasing females' awareness of the virus and the importance of protection. Are there any plans for extending Gardasil's use for men?

BL: The studies are under way in the male population and have been submitted to the FDA as of year-end 2008. We will seek approval here in the United States and elsewhere around the world on the basis of the efficacy data.

Pulse: Do you have an expectation about timing for this indication?

BL: We expect that the FDA will review these data and provide us with a response before the end of 2009. In addition to males, there is a unique opportunity to broaden the use of Gardasil and to target women up to the age of 45, which provides an additional new paradigm for this vaccine. There is a large unmet need with both of these new populations and this represents a growth opportunity which makes the paradigm in adolescent and adult vaccines very exciting.

Pulse: Could you discuss Merck's global vaccine programs and some of the challenges that you have encountered in order to distribute the vaccines globally and in emerging economies?

BL: Across vaccines, whether in emerging markets or in the developing world, solutions which enable Merck to participate and launch products are partnership-based. It will not be a government working alone, or Merck working alone to provide vaccines. We need to work in partnership mode to bring vaccine infrastructure, the political will of the country responding, and other foundational elements together to really make a difference in addressing the case for prevention of cervical cancer or rotavirus gastroenteritis, for example. Merck recognizes in its approach to access in the developing world that all the answers do not rest at Merck. A fundamental approach for all pharmaceuticals and all vaccines is to make sure that we have the right expertise before we move into programs such as donations, tier-pricing or partnerships with ministries of health.

We should also mention our joint venture in Europe with Sanofi Pasteur and our work with CSL in Australia, and various other distributors around the world. In terms of global marketing, alliance management and partnership management and collaboration are critical aspects of vaccine access.

Pulse: In which therapeutic areas is Merck pursuing vaccine development and is there anything exciting in the pipeline that you are able to speak to?

BL: We do have a second generation HPV vaccine, which is very exciting, as well as a program on Staph [Staphylococcus Aureus] which would be an important contribution to the prevention of infectious disease.

Pulse: There is a rise of generic biologics and injectable medications, and a pathway for approving them is developing in the United States. From your point of view, do you feel that generic vaccines will be a risk to Merck, and if so, how would you address this risk?

BL: There are high development and manufacturing hurdles today for biologic products and, as a consequence, you do not see many companies pursuing vaccine development. By virtue of being a biologic process, the products as well as the process are part of the approvable entity. Lot-by-lot approvals and the complex biologic manufacturing of the product make it more complex to copy than small molecule tablets, for example. My favorite point to make on this issue is that many of our original vaccines are not even patent-protected. So, in a world where there are issues of compulsory licensing and intellectual property protection – these measures have only affected newer vaccines. If there were a robust generic marketplace, we would be seeing a lot more generic competition.

"My favorite point to make [about generic competition] is that many of our original vaccines are not even patent-protected."

Because of the recent success of the new vaccine launches, more companies are becoming interested in re-investing in vaccines, whereas historically there has not been an appreciation for the tremendous opportunity in preventative health. We are seeing more interest in developing and manufacturing capability around the world. So, eventually we could expect that companies including Merck will pursue strategies that support low-cost manufacturing.

The era of massive sales forces, free pens, and endless sample supplies is over. Patients and providers alike are pushing back on large pharma's push model, industry tests are underway to find more effective tactics, and consultants are often brought in to create new strategies. Two such advisors are Mark Mozeson and Jim Hall, Partners with Oliver Wyman's Health & Life Sciences practice. Jim and Mark share their approach with The Pulse and suggest that large pharma look to specialty firms for inspiration.

Jill A. Schondebare
WG'09

The Pulse: N.I.C.E., the UK's regulatory body that assesses cost effectiveness of medications, is often referenced as a potential cost control approach the U.S. could adopt. If such a regulatory body were created here, how would it impact the pharma industry and its marketing strategies?

Jim Hall: We've spent a lot of time looking at different programs in Europe where they are already doing cost-effectiveness and head-to-head comparative analyses. We believe that this is going to happen in the United States. It's overdue and companies are going to be held accountable, not just for efficacy but for outcomes - what their drugs should deliver in terms of value. So, if you say it's going to shrink a tumor, then it should shrink a tumor. Not only is it standing by your drug but I think it's also being much more careful about who you prescribe your medications for. Clinical trials are very specific for a targeted group of patients. Yet when drugs are launched, they often go mass market. There is not that discrimination in terms of patient uptake that should probably exist.

Mark Mozeson: Additionally, it's going to change the conversation between the pharma industry and the payers. Right now, it's adversarial. Typically it's a contracting-based discussion about price for a certain product or groups of products. With a cost effectiveness body, it's going to be all about the pharma company being able to make economic claims about how their drug is going to provide value to a patient population. It's going to be more about having the pharma company stand behind their outcomes in order to get attractive reimbursement levels. The relationship will transform from adversarial to cooperative and ultimately to a form of partnering.

Pulse: Why do you think this adversarial relationship exists between payers and pharma?

MM: I would say that both the payers and pharma are historically responsible for it. I think what the payers have done is taken an approach with the pharma companies that focuses on reducing drug spend rather than using drug spend as an effective component of reducing the overall cost of care. On the pharma side, their primary purpose is to drive utilization and price point. Pharma is trying to do everything they can to secure good price points. The payers are working to drive price down and collectively they are ignoring the value question.

"The specialty sales force model should be the rule rather than the exception."

JH: The problem in the payer companies is structural, while I think the problem in the pharma companies is cultural. The payers have not been structured to really approach pharma companies with a view on the total cost of treating a disease. In the pharma company, they have not oriented their way of thinking towards an outcomes focus. Most patients are at best on a 12-month cycle with their insurance company, so nobody is taking a long-term view. If you don't take the long-term view, then you only adjust the cost that you think you can manage in the short-term and, of course, pharmaceutical costs are always the ones you choose.

Pulse: The pharmaceutical industry is recognizing that the push marketing approach, which focuses on the quantity of interactions between sales representatives and physicians to drive growth, no longer yields the returns it has in the past. How have you seen pharmaceutical companies responding to these changes?

MM: In general, the pharmaceutical companies have had a mild response over the past ten years. I think that many pharmaceutical companies have had a fear of a first mover disadvantage, and as a result, they haven't done anything too radical to change the way they go to market. I think what we have seen in the last few years, as a result of a combination of regulatory and cost structure pressures, is that companies have done some of the easy work in the

"I think in the next three to five years we're going to see a rather significant disintegration of the old school approach."

form of reducing the number of sales reps. However, only a few companies have gone beyond that to fundamentally change the model.

JH: The sales model, and we joke about this, is a door to door salesman model. It's a hard sell for medications, and I think it's reached an extreme version of that over the last ten years. When companies were scaling up, they moved away from the specialty sales force that had really good information about drugs – you called on doctors directly because you had something of great value – and now it is more about personalities and just hiring pure sales people just for the sake of the interaction. That was the extreme of push marketing. But when it didn't work and when the blockbusters started going away, companies shrunk their sales forces, and some have returned to remembering why they started them in the first place.

Pulse: Smaller specialty companies that are more nimble are in some ways better positioned to respond to evolving consumer preferences. What are examples of best practices that you have seen emerge from this group?

JH: There are really two models that have been around for a while: the large, primary care sales force model and the specialty sales force model. I think large pharma, in particular, doesn't recognize that the second model could apply to them. The specialty sales force is geared towards information because the speed of information and the dynamic nature of information in specialty drugs, like oncology treatments, are much more than in a primary care drug. This model is used in specialty pharmaceuticals and in the biotechnology firms – Genentech, Genzyme, Amgen, Biogen. With biotechs, it is out of necessity, because they didn't have the money for big sales forces and markets are more compact. These firms had to figure out how to influence through information. For a long period of time, they developed patient registries and learned how to connect to physicians as well as how to connect to patients. Now, I think, a lot of the biotechs are doing a pretty good job of providing that same kind of information to payers to make sure that they understand reimbursement issues. So, the industry, as a whole, has a couple of models.

Pulse: Do you think that these specialty sales force models can be effective for firms operating on a much larger scale?

JH: Yes. Diabetes is a great example. Although it's a disease with a huge population, if you look within it, you can sub-segment. So, you know, it's by age, by weight, by hypertension, and by all of the above. You can sub-segment people with type I versus type II diabetes. There's a lot of ways to do it. Then what you can do is focus on a smaller population to try to effect some change. So, part of it is understanding what the outcome targets for each one of those sub-segments are, and how can you try to effect those changes in a more holistic way.

Pulse: What opportunities exist to reap greater value from all of the marketing dollars spent in the pharma industry? What is a better approach?

MM: This is the issue we feel most passionate about at Oliver Wyman. There are many ways to change the model for the better and when we say better we specifically mean save money, drive revenue and improve outcomes simultaneously. First, as Jim mentioned, the specialty sales force model should be the rule rather than the exception. I think that is a tremendous opportunity for the industry. Another is to really understand that reimbursement guidelines drive prescribing. Hence, why does the industry spend 85% of its sales and marketing dollar on reaching physicians when there are unmet opportunities with patients and payers? Having pharma companies

JAMES ROBERT HALL
PARTNER, OLIVER WYMAN, HEALTH AND LIFE SCIENCES PRACTICE

Jim is a Partner in the Life Sciences practice at Oliver Wyman, where he focuses on corporate strategy and business development. His particular areas of expertise include strategic planning, marketing planning, new business creation, R&D optimization and product development. His industry experience spans biotechnology, medical devices, and pharmaceuticals. Previously, he was President of Wood Mackenzie's Life Sciences Group, a global research and consulting firm specializing in the biotechnology, medical device and pharmaceutical industries. Jim holds degrees in Chemical Engineering and Life Sciences.

MARK H. MOZESON
PARTNER, OLIVER WYMAN, HEALTH AND LIFE SCIENCES PRACTICE

Mark is a Partner in the Life Sciences practice at Oliver Wyman. He has extensive expertise in the pharmaceutical, biotech and medical device sectors. With 25 years of industry and consulting experience, Mark has directed numerous efforts focused on driving strategic and operational benefit to clients in a variety of areas including: commercial operations, clinical development, business development and alliance management, post merger integration and enabling functions such as finance and human resources. Prior to joining Oliver Wyman, Mark was a co-founder of Archstone Consulting, a professional global consulting firm. Mark holds an M.B.A. from the Simon School of Business Administration at the University of Rochester and a B.S. in Mechanical Engineering from the University of Rochester.

capitalize on the range of opportunities [e.g. payers, pharmacies, formularies] that exists rather than focusing exclusively on getting their sales and marketing dollar towards reaching physicians would be a better use of resources.

Pulse: Have you seen any of the large pharma companies currently taking on any of these approaches?

MM: We have. I've seen a couple that have taken a total look at their market, trying to understand how to bring the right capabilities to bear on a product plan in order to find these other areas of opportunity and make dramatic changes to their sales forces while rebalancing their use of assets. But beyond that, there are dozens that really have not done very much other than make some small adjustments in the number of sales reps as a result of products just not requiring the same level of attention, which is often as a result of patents expiring or where they are in their life cycle.

I think looking forward five years from now, the bigger risk that pharma companies face is the risk of doing nothing and finding themselves in a position where as a result of not responding to the regulatory and cost pressures, they are behind their competitors.

Pulse: Despite its decreasing effectiveness, do you anticipate the large sales force style of marketing to continue to dominate in the next 5 to 10 years? Can you give a time frame for when you think companies will begin to adapt?

JH: I think in the next three to five years we're going to see a rather significant disintegration of the old school approach. I think you are starting to see the shift now. Mark spoke earlier of the first mover disadvantage, which is quite prevalent in the industry, but I think as soon as you see one major pharma really be very determined in [changing] what they're doing with their sales model, then others will follow.

MM: There are a few other dynamics. I would agree with Jim that the camel's back will probably break in about three to five years, but one of the other factors accelerating that is the fact that the doctors are pushing back. The doctors are fundamentally not responding very well at all to the frequency in reach approach, the low value interactions with reps, the gifts, and the conference sponsorships. As a result, groups around the country are looking at these practices and laws are starting to change. So I think that there's going to be regulatory pressure as well as customer pressure from the physician community to say that this is not necessarily how we want the drug industry to market to physicians. That will ultimately force the industry's hand [and push] dramatic change.

What will be the largest transformation to the health care industry over the next 20 years? Interviewees take us beyond 2009 and share what they hope or predict for the future of health care.

"Simple. I will leverage a quote from George Halverson [CEO] at Kaiser Permanente: "Today's world has 9,000 different codes for reimbursing doctors for doing procedures – for fixing something that is broken – but zero codes for prevention." My hope is that twenty years from now we will have a better balance between treating and preventing illness."
—Peter Neupert, VP, Health Solutions Group at Microsoft

"In the year 2030, my hope is that there are people all around the world who may not even know that cervical cancer was once the second leading cause of cancer death. In countries like Australia, where broad-based immunization strategies have already been implemented, by 2030 we may have very clear evidence of a path toward eradication of the diseases caused by the HPV types covered by vaccines, including cancer. That is my hope."
—Beverly Lybrand, SVP, Vaccines at Merck & Co.

"I think the key change in the market will be the absence of a homogenous group that looks like large pharma and a homogenous that looks like biotech. It's all going to look much more heterogeneous as different companies make different strategic choices. Whether it be in terms of their focus on primary care or specialists, or to what degree they diversify, or how much they engage in collaboration with other companies. Much will come from how successful they are in the non-Western parts of the world. Furthermore, if a large pharma isn't able to restart a stalling discovery engine, I can see a shift in their model occurring to one that is more 'search and develop.' Overall, if you take this wide range of parameters and mix them together in different ways, you could end up with a very different picture of what a pharma company, and therefore what the pharma industry, might look like."
—Dr. Yvonne Greenstreet, SVP, Chief of Strategy and R&D, GlaxoSmithKline

"It is a focus on prevention. What is killing us for affordability of health care is demand. We have too many people who need too much, and it is becoming extremely costly and ultimately unaffordable. It is not about one technology. It is not about imaging and noninvasive screening. It is not about personalized medicine and genomics because I think those ultimately will help a fraction of the population here, or a fraction of a population there.

It is popular to demonize the drug and device companies for charging high prices. Well, it costs a lot of money to develop those drugs, and it costs a lot of money to make a defibrillator. So, you know, we are demonizing the solution but we are not demonizing the excess demand for health care, and in the end we have to have a population that is born and raised on the notion that you have to take good care of yourself. Then, for those who are unlucky enough to require high intensive medical therapy over time, the therapies will be extraordinarily advanced, and we will be able to apply them to an appropriately small portion of the patient population that needs them. We cannot afford to keep going as we are now with an overweight society that abuses itself and then complains when unlimited therapy for all is too expensive."
—Paul LaViolette, Venture Partner, SV Life Sciences

"I think it will be more access to quality health care leading to earlier and more effective treatment. This is going to happen in steps, but if this is done well, it will be a revolution. Health care will be considered a basic need like food or clean water. It doesn't stop at access. Follow up measures have to happen, but you have to get to that point. Right now access is the bottleneck."
—Omar Ishrak, President & CEO, GE Healthcare's Clinical Systems

"If we look back 20 years from 2030 and think about the big changes that happened, we would be talking about the fact that a lot of radical transformations did not actually happen. We had the genomic revolution where people were predicting delivering gene therapy. What happened is that we know what the genome consists of, but we don't know a lot of what it does. We found out that there is the genome, proteome, metabalome – the human body continues to surprise us with its complexity! We look at the promise of stem cells today, the ability to proactively create tissue, and that promise is extremely exciting. But we don't know what the dangers and or the challenges will be. Surprisingly, 20 years is not enough time in the pharma space. So much of it is a serial process – you can't do phase 1 and 2 at the same time. It is a slow process, because you have to take such good care and be so thoughtful about experiments with people, as you should. 20 years is not that long a time."
—Jonathan P. Northrup, COO, Jubilant Biosys

"Looking back from 2030, I would say that there was a health care revolution in 2009 and 2010, and that the current system fell apart, basically. The whole notion of our current method of reimbursement for health care dramatically had to change. The first thing that went out the window was fee-for-service, and as a result, there was a disaggregation of the insurance companies. Consumers and patients got reimbursed for what they actually needed when they actually needed it. That drove a complete revolution in the pharmaceutical industry. Any product that had any kind of competition of maybe two more products would see their price just dropped to the floor and only truly specialty drugs could keep specialty prices. Fewer and fewer new drugs will be coming on the market despite increase spending in the industry for R&D. And as a result of having higher levels of unmet need in the industry, there is a lot of pressure on pricing."
—Mark H. Mozeson, Partner, Oliver Wyman

"I would like to see a big change in the pharmaceutical structure. So 30 years from now, what I would like to see is that companies were broken up… no more were there mega-pharma companies across 10 therapeutic areas but they were broken into small, more nimble organizations that actually focus on patient outcomes. And what we saw was a huge increase of new drugs being developed, approved and brought into the market. That's another reason why the prices started to drop –the pharmaceutical companies became a lot more effective in how they develop and produce drugs. Basically, pharmaceutical companies adopted the methodology that biotech companies have been using for 20 years."
—James Robert Hall, Partner, Oliver Wyman

"Personalized medicine and cell therapies will be a reality. I think that cell therapies and personalized medicine will go hand in hand, because in many cases you will either be using cells from your own body and modifying them and putting them back in, or using cells from a compatible person. Identifying what genes are affected by medications, and then tailoring the medication to the DNA structure of people is absolutely going to become the standard. I wish I could be around to do tech transfer on some of those things."
—Michael J. Cleare, Associate Vice Provost, Center for Technology Transfer at the University of Pennsylvania

"I don't know, and that's the futurist talking! It's really hard to change the culture of these places. The culture is inherently fragmented, which is a big, big message in my book. Nursing continues to function as an entity unto itself, as do each one of the clinical specialties. I mean there has just been so much fragmentation, and I wish I could see that changing more quickly, but it hasn't changed meaningfully in the 32 years that I have been in the field. I'd like to think there is an IT solution, but it's really culture."
—Dr. Jeff Goldsmith, President of Health Futures

SHIFTING GROUND: NEW RULES FOR MEDICAL TECHNOLOGY INNOVATION

Paul LaViolette brings a unique perspective to innovation in medical technology. His recent work as COO of Boston Scientific exposed him to multiple aspects of the industry, from deal making to working on one of the largest device launches in history. In this interview, The Pulse speaks with Mr. LaViolette about major industry developments and their anticipated effects on various med tech players.

Emily Cooper WG'10
Jonathan Maack WG'09

The Pulse: When you look at the increasing cost of taking a device to market, does this give more power to the larger players like Boston Scientific and Medtronic versus smaller innovators?

Paul LaViolette: I think it does. I think rising costs intensify risks and make it harder for small companies to make it to market alone. This varies from company to company, technology to technology, market to market. But there are some venture capital firms, as an example, that will not fund a company that is pursuing a PMA [Pre-Market Approval] device just because those restrictions you cite are getting to be so substantial, which turns into more time before approval and more money spent.

So, the amount of capital you have to raise and invest, and therefore the amount you have to exceed in a liquidity milestone, just starts to defy gravity. So, I really do think that [the regulatory environment] does play more to the hands of the large-cap players, who cannot grow entirely organically.

"If a physician actually has a hand in inventing a technology, it is improper for him to be the principal investigator of the trial…"

I think the timing with which large cap firms work with innovative entrepreneurial companies may change. Small companies may take it through the first couple of phases of development and then seek strategic partners to take them to the next couple of phases.

It makes for strange bedfellows a little bit, but there is a fundamental premise here that the small companies still need to innovate and the large companies need to bring the financial and the infrastructure power to finish the deal. If they do not work together, innovation will slow because we know the big companies are not really capable of fueling all of the start-up pipeline activity, and yet we know all those entrepreneurial companies cannot bring their technology development all the way through to commercialization.

I think the environment will require more partnering. The raw financial demands of these large-scale clinical trials are daunting. Even with the "good news" of having more post-market trial obligations, the bad news is that all of your early post-launch cash flow is consumed by durable clinical requirements. Profitability is pushed out that much further into the future and it becomes unsustainable for small companies. So, I do think it tilts the scales a little bit for large companies.

Pulse: Let's talk a bit about drug-device convergence. Given the recent issues around drug-eluting stents, do you see the industry's view on combinations changing at all?

PL: My position all along has been to be very, very careful about the presumption that there is a new era, and that that new era combines devices with active agents, and that this combination is the wave of the future. I have actually never thought that drug-device convergence was a "wave," probably because I was sobered by development reality, albeit successful, within Boston Scientific.

We happen to have the biggest drug device combination product ever, but we have had many failures along the way. We worked on stem cell delivery systems and we have worked on a variety of other drug delivery technologies through the years which have not panned out. So, we learned how hard it was to do. We learned that before we got into drug-eluting stents. Some of the scar tissue we gained from these early failures probably helped us to succeed in drug-eluting stents as a small device-

PAUL LAVIOLETTE
VENTURE PARTNER, SV LIFE SCIENCES

Paul LaViolette will join SVLS (SV Life Sciences) in January, 2009. Paul brings over 28 years of global medical technology marketing and general management experience. Paul was most recently Chief Operating Officer at Boston Scientific Corporation (BSC), an $8 billion medical device leader. During his 15 years at BSC, he served as COO, Group President, President-Cardiology and President-International as the company grew revenues over 20 times. Paul integrated two dozen acquisitions and led extensive product development, operations and worldwide commercial organizations.

Paul previously held marketing and general management positions at CR Bard, and various marketing roles at Kendall (Tyco). He served on the boards of Urologix, Percutaneous Valve Technologies and AdvaMed, and currently serves on the boards of TranS1 and Direct Flow Medical.

Paul received his B.A. in Psychology from Fairfield University and his M.B.A. from Boston College

only company relative to the scale and integrated pharma competencies of J&J at that time, but I think we had to be far more sober on the convergence concept all along.

My premise for drug-device combinations is that you should default to a combination product to achieve a clinical end only as a last resort. You should never allow the allure of that concept to pull you in that direction unless you have tried and failed at every other, simpler approach. When you look at the compound complexity that is brought to a program by having drug and device combined, you realize it is not worth it unless the clinical deliverable can only be achieved through the combination, and only when the market is substantially larger than average because the investment will be substantially larger than average. The risks are much higher than with conventional device development and therefore, the particular payback dynamics of your opportunity have to be much larger than average.

Pulse: Do you see recent changes in the rules around physician-industry partnership as negatively affecting the pace of innovation?

PL: I honestly do not think so. I may be overly optimistic about how this plays out, but I do not think there is any question that conflicts of interest are real, and they have to be handled much more professionally than in the past. The medical device industry has grown up. You have new technologies that roll out now and can treat 100,000 or 500,000 patients. If there is any perceived weakness in the data or the methods of collection, then the entire basis for believing in the new therapy is put into question. Scrutiny is high, the stakes are high, costs are questioned, everything is scrutinized much more tightly and so, it really calls for transparency in any area of potential conflict.

I do not believe that we can have innovation in medicine without close partnership between physicians and technology companies. You would never develop a fighter plane without test pilots, it's just inconceivable. When you think about the essence of medical technology, it is devices as an extension of a physician's hands and often their vision. So, it is essential that physicians be involved in the process. As that innovation process has matured, it's not surprising that innovative or entrepreneurial physicians have devised breakthrough concepts and sought involvement in their development.

Given that, the question becomes, how do we properly involve physicians? How do we keep them fully engaged in the process while in no way endangering the follow-on credibility of their contribution? A patient undergoing a procedure must feel that the technology is properly validated and their treating physicians are choosing the appropriate technology based on objective evidence, and not based on receiving a piece of the action. What the industry has to worry about is distortion. For all of the right reasons, we want physicians engaged but must avoid having that work distorted based on financial involvement.

Pulse: You might get disagreement from some physicians on that last statement. Do you have any thoughts on this physician pushback to the new norms that are being established?

PL: Physicians will always tell you that they personally can rise above the conflict of interest. In other words, they see themselves as being able to transcend human behavior. But truthfully, they can not. So, there is a bit of ego in there that has one believing that "even though technically I am conflicted, I am not going to let it affect me." So, I think you need clear boundaries. Frankly, when you think about where the disclosure and remuneration lines get drawn, they get drawn according to how much money a doctor can make from their contributions, be they training and communication work, an advisory role or proprietary invention. There also needs to be clear separation between a physician's role in an entrepreneurial activity versus their role as a clinical investigator or even as a practicing physician. The patient has a right to know the physician selecting a device or procedure for their therapy is not conflicted by his personal interests in that device.

If a physician actually has a hand in inventing a technology, it is improper for him to be the principal investigator of the trial and it may be improper for him to even participate in the trial. It definitely would be improper for his data to be more than, let us say, five percent of the final data set used to determine whether that device performs as intended. There are a lot of physicians who would look at that and say that that is an unreasonable restriction, but I will tell you that is completely objective. It is based on well-reasoned scientific method, and it is absolutely not asking too much. Physicians are coming from the historic perspective of actually having their cake and eating it too, and what we are saying is you cannot do that any longer.

Pulse: The Riegel versus Medtronic judgment limits patients' ability to file personal injury lawsuits that challenge the safety and effectiveness of devices that have been reviewed and approved by the FDA. It also indicates that the labels companies develop should be considered adequate if they receive FDA review. How do you expect the ruling to change the industry?

PL: Its impact is still to be determined. As soon as the Riegel decision was handed down, some members of Congress said that they would push for a legislative override. That will not happen now with this session of Congress so will have to wait until next year.

The Supreme Court has now heard the Wyeth case, which has a similar theme for pharmaceuticals. There is a fundamental difference between those two cases in that, specifically within in the medical device amendments, preemption was expressly contemplated. It was written in. It was presumed to be the operating premise of the medical device industry and that was not the case with pharmaceutical regulation.

I think there are two practical arguments surrounding preemption. If you are in favor of overriding the Riegel judgment and overriding preemption, then you believe that a patient with a poor clinical outcome should have legal recourse against the device manufacturer in state court even in the instance where the device was manufactured properly and performed as expected. The theory is that the threat of negative consequences motivates companies to do the best job. I believe this is overly protectionist and would do more harm than good to overall patient populations.

"My premise for drug-device combinations is that you should default to a combination product to achieve a clinical end only as a last resort. "

Overturning preemption may actually lead to a lot of perversions in the system. The counter argument is that, emanating all the way back to the Constitution, in certain instances we benefit from the superiority of one federal system over a decentralized state system.

The best example is the Federal Aviation Administration. When a plane is going to fly coast to coast, we all want to know that they have the same take off and landing system in operation in New York as in California so that planes know whether to take off to the left instead of to the right. It only makes sense that a common federal standard should trump the state's local standard in such instances.

Continued on PAGE 38 >

OFF THE BENCH, INTO THE GAME: NEW MODELS FOR TECHNOLOGY TRANSFER

Michael Cleare heads the Center for Technology Transfer, a division of the University of Pennsylvania. Its mission is to transfer inventions and innovative knowledge to outside organizations for the benefit of society. CTT serves as a bridge between Penn researchers and industry, ensuring that good ideas are brought to market rapidly while protecting the interests of the institution and inventors. Mr. Cleare speaks with The Pulse about his experiences in industry and Penn, highlighting the value of academic insight and how top universities are going from technology-specific negotiating to innovative, longer-lasting partnerships with industry.

Neil Parikh
WG'10

The Pulse: What are the main objectives of the Center for Technology Transfer?

Michael Cleare: The Center for Technology Transfer has two primary tasks. One is soliciting inventions from the faculty. We have regulars who just bring them in and we also have outreach efforts to try to round up inventions. Our faculty is focused on doing research, and sometimes they don't realize where inventions can go beyond that. We do have more and more faculty very interested in the whole idea of translation of research and getting societal benefit from their research possibly when we can.

The other is that we decide which of these inventions are worthy of patenting. Because we look at 250 to 350 inventions a year, we have to use a sophisticated process to do this. The test we apply is much less about whether the science is any good, but rather whether we can we see the signs leading to a product or a process that is tangible and commercializable. If that's the case, then we make sure that the idea, even if it's in a crowded field of activity, is patentable. What we're trying to do here is get the technology out for the benefit of society, but at the same time get a reasonable return for the university and the inventors.

Pulse: What technologies does CTT currently cover within the health care space?

MC: Approximately 75 to 80 percent of our inventions tend to come from the life sciences, and if you included medical devices in that, the number might be even higher. For the last ten years, pharmaceutical firms have continued to come to UPenn to explore potential drug opportunities.

The hospital also produces a lot of medical devices. Not only do we have professors developing medical devices, but we also have surgeons inventing medical devices. While operating, they realize they need something, and they actually invent something in process that will make their work easier when doing a particular surgical procedure. They then can draw on the engineers that can help make it happen.

Diagnostic tests are also something that people are looking into a lot these days. This is particularly important given the widely held beliefs about the importance of personalized medicine. In this scenario, what one knows about a person's genetic make up is important to understanding how drugs and pharmaceuticals affect them, what the mechanism is, and how they operate with respect to particular genes or particular pro-genes. The more they know about this, the more they determine which medicines are vital for which diseases, in particular cancer. Some drugs are really good with forty percent of the cancers, but ineffective with all the rest. Of course they're realizing more and more some of the fundamentals of that. As people begin to realize the potential of those markets, they are continuing to look at diagnostics.

"In the '90s most of the technology transfer was done [with] licenses… [today it is being done] through start-ups. "

Pulse: How does CTT help get technologies out of academia to the market?

MC: In the '90s most of the technology transfer was done by a license system. From the mid '90s onwards, a rapidly increasing means of transferring technology has been through start-ups. We participate either by being directly involved or by encouraging start-up companies. This has become more and more important as industry has tended to become a bit more risk averse, especially in terms of investing in university technology.

Incremental technologies that attempt to add to what's already out there have a much better chance of being licensed. You probably should license it because a company has the infrastructure needed to commercialize a product. But so much of the technology here at Penn is what I call new platform technology or concept technology that has a lot of potential applications but requires validation and reduction to practice.

Pulse: What determines the license value of a technology?

MC: Value is in the eye of the user. It is how it can work for somebody else, not how you think it could work. So my philosophy is if there is a market, you listen to what other people are saying.

One of the lessons I would offer to people is that it's sometimes surprising which of your patents turn out to be the most lucrative. All patent holders should take the total society benefit point of view. For example, say you consider licensing a new target for some pathway. If you look at that target, it looks as if you may be able to have a small influence on something big. Yet this target could be worth a lot, even if a huge amount of extra work has to be done to take it where you want. If you're able to track it, you might find that down the road, that little piece of knowledge has helped to produce something really important.

The transfer of this knowledge to external parties is the key to bringing things to market. Sometimes, it is very surprising which of your patents are going to be commercially successful in terms of revenue generated.

Pulse: What is the motivation behind direct commercialization?

MC: Usually [it happens] when a technology is very early stage and you have to validate it to a level that makes industry happy. Of course, anybody can validate an idea if she has the funding. The funding gap is the gap between the technology that tends to come out in a professor's lab and the degree of validation that's necessary to really reach the market.

The challenge is that usually the federal funders don't want to do that. Usually these ideas only need to be funded in a very incremental way. An initial funding could be as little as half a million dollars or a million dollars, which is really just proof of concept and getting to a state of validity that would enable a real Series A round where you bring in outside investors. Of course, we'll be lucky if we do find breakout start ups at the university, but we have at this moment about twenty startups that we're trying to get going, of which the biological sciences account for probably eighty percent.

Pulse: Why would large firms come to universities as sources of innovation rather than acquiring other firms or running their own labs?

MC: I see a trend starting from the pharmaceutical industry in particular and maybe health care in general. Pharmaceuticals are taking the lead when coming back to universities and the reason is, I think, driven by the pipeline issue.

I think this is a very important point to make, that the pharmaceutical industry has been missing a link for some time. The industry has multiple research labs, multiple testing capabilities and development capabilities. But I was in industry for quite a while, and I saw that industry research tends to follow a certain path that has been laid as to what you are going to do. If pharmaceutical scientists have been working on a particular area and they see something, it is not as easy to get together and swap ideas. They have a lot more structured interchange.

"[Professors] follow their own noses…and have a lot more unstructured interchange [which] leads to paradigm shifts in technology."

In universities it's much more serendipitous. Professors are basically free agents, they follow their own noses.

MICHAEL J. CLEARE, PH.D.
EXECUTIVE DIRECTOR OF THE CENTER FOR TECHNOLOGY TRANSFER AT THE UNIVERSITY OF PENNSYLVANIA

Michael J. Cleare is the Associate Vice Provost for Research and the Executive Director of the Center for Technology Transfer at the University of Pennsylvania. In this role, Dr. Cleare leads outreach to faculty, as well as collaborations with industry and the investment community.

Prior to his current role, Dr. Cleare managed Columbia's highly successful research-commercialization endeavors for seven years. He was previously employed for three decades by Johnson Matthey, a world leader in advanced materials technology. He has held a number of senior executive positions in research and development, new business development and division-level management.

He received his B.S. and M.S. in Chemistry from Imperial College and his Ph.D. in Chemistry from the University of London. He pursued post-doctoral studies at Michigan State University with a focus on platinum anti-cancer research. Dr. Cleare was a named inventor of Carboplatin, one of the most widely used anti-cancer drugs. He has published more than 40 articles and papers and holds 10 patents.

If they see something, they are willing to branch off. Professors get together and swap ideas. There's a lot more unstructured interchange which leads to a lot of the paradigm shifts in technology. It's a group of very intelligent people and somehow that seems to produce really brand new ideas. This makes sense, because the whole aim of a university is to push back the frontiers of science. They aren't trying to build a portfolio in a particular area - they are just following what looks interesting. And there is a lot of value in that approach.

Pulse: What do you see in the future of commercializing university innovation in the health care space?

MC: In the end, I think the pharmaceutical industry should have ties with universities because it's a very inexpensive opportunity. Getting a great idea from a professor to a potentially promising stage of development can cost as little as $250 to $500,000, and will get you to a stage where there is significantly more confidence that an idea has some legs.

So suppose a pharmaceutical company came to this office and said, "We will give you $5 to $10 million a year and you can use it in up to $500,000 parcels. We want to sit around the table and help you select which ideas to work on, and if we put money in to bridge that gap, we get the first option to purchase that technology."

This sort of arrangement with five top research universities would cost the pharmaceutical company $25 to $50 million a year, which is not a huge expenditure when compared with overall R&D spending. That would give them a way to tap into some of the paradigm-shifting ideas from academia.

Pulse: If the university is the unstructured environment that you described, does pharmaceutical funding change motivation in terms of projects that you pursue?

MC: That's a good point. I think if these partnerships go through the technology transfer route, where we are presenting work that is already in progress, there is no issue at all. There just has to be lines in terms of what they [the pharmaceutical industry] get access to.

In other cases, where you are exploring an out-and-out alliance, it has to be understood that academic freedom is built into that. You cannot have the pharmaceutical people dictating what is done. You have to protect academic freedom – control of the research program has to be totally in the hands of the scientists.

SPECIAL FEATURE: RETHINKING EMERGING MARKET BUSINESS MODELS

India is a prominent emerging market for health care, where change has been rapid and the numbers involved, whether market size or talent pools, are staggering. While GDP growth has averaged 8.5 percent over the past five years, health care expenditure per capita has nearly doubled in the same period. The entire health care market, currently valued at $35 billion, is expected to more than double in less than three years.

One of the most visible investment areas has been the development of private hospitals to cater to medical tourists, India's elite and the rapidly growing middle class. Major players such as Apollo Hospitals have been leading the way on infrastructure projects of such immense scale that some of the newest facilities are labeled "medical cities." Yet meanwhile, entrepreneurs are beginning to identify new emerging markets within this emerging market and are looking to tap into India's largest asset: volume.

Addressing New Populations

The economic boom in India has primarily been limited to the major cities. Yet nearly seventy percent of the population resides in rural India. Poor infrastructure and access to these areas have shielded it from both the positives and negatives of growth. Companies are beginning to identify technologies that bridge the access gap and tap into a large, previously underserved group of patients. GE Health care recently announced a $200 million investment in rural markets capitalizing on innovative diagnostic technology. Omar Ishrak, CEO of GE Health care Clinical Systems, talks to *The Pulse* about the company's motivations and strategy in a first-of-its kind project.

Developing New Capabilities

India has a long-established pharmaceutical industry focused on cost-effective drug manufacturing. Drug development has been a comparatively new focus area for the nation, but a perfect storm of a struggling global pharmaceutical industry coupled with India's cost and volume advantages is opening the door for entrepreneurs to enter this space.

A major driver of change is that India's scientists and physicians are staying put, unlike previous generations of experts who were often lured away by opportunities overseas. The current transition in national health trends from communicable infections to chronic diseases is creating a disease profile more similar to that of the West. When you add in the large patient pool, the potential for domestic clinical trials becomes quite strong.

At the same time, global pharmaceutical firms are in search of new drugs to fill their pipelines (See *The Pulse* interview with GSK's Head of R&D for more on pipeline development strategies). While new molecule innovation appears to be limited in India, the country does provide a potential venue for low cost, high quality research and development operations. Jonathan Northrup, COO of Jubilant Biosys, gives his thoughts to *The Pulse* on this promising opportunity. His India-based company is an "integrated discovery collaborator to major pharmaceutical and biotech companies." Jubilant Biosys recently announced a shared-risk partnership with Amgen, a California based biotechnology company, to develop a portfolio of drugs for new therapeutic target areas.

Neil Parikh
WG'10

The Pulse: What is the attraction of India for GE Healthcare?

Omar Ishrak: Let me put this whole thing in perspective: when you look at health care, something like fifty percent of the dollars are spent in the United States. Of the portion outside the US, the majority of that market is in Western Europe. Ten percent of world's population gets ninety percent of health care dollars. Only about two percent of the dollars are going to markets like India, which means there are billions of people underserved in health care. These countries, like India and China, have large rural populations. If one wants strong growth from a business perspective, you have to look at this opportunity.

We are focused in India because we already have a presence there, and our presence is broad. For example we are the largest player in ultrasound and we've also been there in local manufacturing for the past fifteen years. Even before it became an attractive place for other multinationals to go there, we had been operating.

Because of this presence, we already had reach to second and third tier cities. In India, first tier cities are similar to those in Western countries in terms of their model of health care delivery and need for high end equipment. Second tier cities are places where the nature of practice and work flow is similar to the Western model, but they want more affordable equipment. We develop value products for that market that follow the traditional way of delivery. For the rural market, we have to create the model. We have to invent the equipment and customize for local needs. In these markets, there is the need for a total system solution, for which we can't simply drop our products.

Pulse: How can technology change the way care is delivered in India?

OI: To use an analogy, cell phones revolutionized telecommunications. Twenty years ago, if someone wanted to modernize telecommunications in India, they would have thought to lay landlines all across the country. This was not practical. With the advent of cell phones, simple yet sophisticated technology was available to anyone. We think there are similar opportunities in health care to develop affordable access.

In addition we find that a lot of our technology, especially with our established resources of technical and engineering skills sets, gives us the ability to create unique products to serve that market. Another advantage is that our engineering teams are connected to their peers around the world. The Indian engineering team is connected to teams in the United States, China, and others. The virtue of that is having access to a great deal of technology, which they can leverage to suit the lower cost platform for India. This access to global technology can revolutionize the way health care is delivered and is being translated for needs to Indian market.

"Only two percent of the [world's healthcare] dollars are going to markets like India…there are billions of underserved people. "

One example is in ultrasound. We are in the process of developing an ultrasound machine that is more compact and mobile than conventional machines. With this technology, one of the areas we are focused on is screening women for adverse conditions for pregnancy. But obstetric ultrasound is only an entry point. Ultrasound is being used in a much more widespread way, particularly in emergency settings. They do not need the larger machines and formal radiology readings. They are looking for quick assessment and guidance. Leveraging this trend, what we are doing is creating simple products that can be used in these scenarios and fashioning them for rural settings, where you need simplicity, portability, affordability, and robustness. We have the technology; we simply need to apply it to a different setting. Our vision is to make ultrasound the first line of diagnosis and assessment for any illness, the way the stethoscope is used now.

OMAR ISHRAK
PRESIDENT & CHIEF EXECUTIVE OFFICER, CLINICAL SYSTEMS, GE HEALTHCARE

Omar is the President & CEO of GE Healthcare's Clinical Systems, a $4.9 billion division with a mission to develop innovative technologies that improve clinical precision at every point of patient care. Under Omar's leadership, Clinical Systems has sustained annual double-digit growth over several years, with these diverse technologies reaching more patients and healthcare professionals around the world. Clinical Systems comprises of GE's Ultrasound, Monitoring Solutions, Interventional and Diagnostics Cardiology, Bone Densitometry, Maternal-Infant Care and Life Support Solutions businesses. Omar joined GE with more than 13 years of technology development and business management experience, holding leadership positions including Senior Vice President of Worldwide Marketing and Product Development at Elbit Ultrasound Group and various product development and engineering positions at Philips Ultrasound. He earned a B.S. and obtained his Ph.D. in Electrical Engineering from the University of London, King's College.

Pulse: What are the motivations for entering the rural market?

OI: Our motivation is two-fold. One is clearly to provide better health care and to pursue work with a sense of purpose. We are also a business and have to find business opportunities. Health care is really a collection of a million procedures. The procedures might be small and not seem initially lucrative. But when each one of those procedures is multiplied by the millions of times it is done and is translated to dollars, there is a huge opportunity. That's why health care in India is a great business area. And developing technology for this market is less costly for us since we can pull on our large library of technology and expertise. In that sense the incremental effort in relative terms make it more practical for us because of our breadth and scale.

Pulse: How does payment work in these markets?

OI: We have to develop the system, but we have to create affordable care first. There is a bit of the chicken and egg problem there. Cell phone providers didn't arrive until after cell phones were developed. So we believe that after analyzing the care cycle and finding ways to introduce appropriate technology that improves access at the right points, the financing system will emerge to compensate us for that. Right now in India, a large number of procedures are paid for by the patient. There is potential to develop better insurance models. If we improve the access, the different methods to pay for it will evolve. I can't say that I exactly know the path. We have many people looking at developing this system in innovative ways. But I do know the system of funding is tightly linked to technology.

Pulse: What have been the major challenges in entering this market?

OI: So far the challenges have been around finding partners that have the same sense of purpose in the same area. We have to find the right mix of interests.

"We have to prove that we want to find a solution, not just sell a hundred ultrasound machines."

One example of an area that we think we can change is the way health care can be delivered. We are working with private health care chains that have a desire to do outreach in these rural communities. There is a lot we can learn from these partners and many ways in which they can benefit from our capabilities.

There is also an issue of being occasionally viewed as someone that just wants to sell equipment. We have to prove that we want to find a solution, not just sell a hundred ultrasound machines. There is a dose of skepticism, but we have to present ourselves the right way. We must show we want to work together to develop a system that is holistic and makes sense. Finding the right partner for this is not that simple, but it can be done.

Continued on PAGE 38 >

Neil Parikh
WG'10

The Pulse: What is the attraction of Asia for pharmaceutical manufacturers?

Jonathan Northrup: I think there are several advantages to Asia, and I think they are complimentary to the West. What a lot of people are trying to do is find the right East-West model to take advantage of what both have to offer. India and China are educating an enormous number of scientists and physicians, definitely more than the West. So the trend is accessing talent globally to get as many minds on the most important problems. Also, these are markets that are growing very rapidly. These countries are developing an enviable middle class. In not too long - certainly by 2015 - people believe China will have more middle class than the US. India, in a similar fashion, will have equal or more consumers than us. The middle class might not be quite as wealthy and the intensity of consumption might be different, but it will be a considerable force in the world. Four billion people – two-thirds of the world's population – is in Asia. Finally, if you want to be efficient in clinical trials, you need to go where diseases are that you want to treat. Certainly you have to think of Asia as an important piece of that dynamic, because it is such a big population.

Pulse: How important are cost advantages to the case for Asia?

JN: Pharmaceuticals are definitely looking to take advantage of the disparity in overall income level. The middle class makes between $10,000 and $30,000, versus here in the US where it is nearly $100,000. But I don't think it is exclusively about cost. Pharmaceutical companies are also interested in discovery and the ability to tap thought and innovation. They also benefit from a willingness, with some caveats, of patients to participate and be involved in clinical trials. It's all about all these things coming together. Cost is a factor but definitely not the only thing bringing people to Asia.

Pulse: What are some of the challenges of operating in Asia?

JN: The challenges for me have mainly been about integrating the enthusiasm of Asia with the maturity of the West and understanding how best to communicate in these two environments. It is subtly different than how we would work just in the West. That is an important aspect that people need to recognize.

"The US is not less important, but its dominance will be shared with Asia. "

Also, different countries have different strengths that allow companies to tap diversity in a synergistic way. For example, India has wonderful chemistry. The biology is great too, but it is harder to come by especially when compared to China. On the other hand, India being both the world's largest democracy and English speaking provides a pool of entrepreneurs and a legal system that is similar in many aspects.

Pulse: What is the quality of expertise available in these markets?

JN: In Asia, drug development and pharmaceuticals are relatively new. India has a very smart, educated, and talented work force, but they don't have experts in biopharmaceuticals. Roche, Novartis, Lily, Pfizer, GSK - they have been doing drug development for a great length of time - over one hundred years. That experience in understanding drug development is fairly unique and really is not that available. India gets that experience from expatriates coming back from working with Western companies, and from Europeans and Westerners relocating to India for the opportunities in this space. Indian companies want to work closely with Western collaborators to build and enhance the competencies and knowledge in drug discovery and drug development that comes from years of doing drug development. This is hard-won knowledge that involves understanding previous failures and knowing how to be successful.

Pulse: Do you see this movement towards Asia as a transition away from the United States?

JN: I don't agree that it is a transition away from the US as much as it is an unleashing of a part of the world that historically did not have an opportunity to participate. The US is not less important, but its dominance will be shared with Asia as the number of people and the efforts of these people begin to surface.

JONATHAN P. NORTHRUP
COO, DRUG DEVELOPMENT, JUBILANT BIOSYS

Mr. Northrup is currently the COO of Jubilant Biosys, an India-based organization that provides integrated discovery collaboration to major pharmaceutical and biotech companies. Prior to joining Jubilant Biosys, Mr. Northrup was founder and CEO of Horizon Biotechnologies LLC, a consultancy that offers services to Asian companies in the biotechnology and pharmaceutical space.

Prior to Horizon, Mr. Northrup held a number of management positions across Eli Lilly and Company in a 28 year career, including Director-level positions in business development and strategy, strategic asset management, corporate business development, market plans and research and new product planning as well as additional positions in pharmaceutical sales management and marketing management.

Mr. Northrup is a frequent speaker in pharmaceutical industry forums, and is published in two books on the business of healthcare. Mr. Northrup holds an M.B.A. in Finance from the Wharton School of Business at the University of Pennsylvania, where he graduated with distinction, and a B.A. in Economics from Northwestern University.

The US has a special place in the world that it will continue to have. The US has the ability to redesign itself to the new realities of the world, and I hope to continue to allow those forces to play so we continue to change ourselves the right way to maintain our presence and capabilities.

Historically in the US, when we have seen turbulence, we have been able to change and take advantage of the new realities of the world and succeed. The US is the bastion of technology and new ideas. It has always been our strength that we create and take advantage of new models. We create the innovation by pulling together academia, government, and business in really good ways. This is a sophisticated aspect of our economy that allows us to win in the global marketplace.

"We'll see consolidation in the pharmaceutical business…[and] will wind up with no more than five to ten companies able to do everything."

We can still do that, but we have to realize that we are going through a transition and things are going to change. Other parts of the world are starting to assert their advantages and we have to learn how to work within this new world. I think if we can do that, we will continue to be a very strong country and successful going forward.

Pulse: How do you manage both markets?

JN: To manage both markets requires an additional level of sophistication. The main thing in our model is that we wanted to do work under offices of both the US and Indian regulatory agencies. We do not plan on, and are currently incapable of, taking molecules all the way to the end game of registering new drug application, phase 3 trials, and marketing. We don't have the infrastructure for that. We see our role as collaborating with pharmaceutical firms to take the molecule the rest of the way.

Given that business model, we want to make sure every aspect of what we do is solid from the standpoint of both agencies. This gives large pharmaceutical firms comfort that we went through significant efforts to ensure that a company taking a molecule to the next stage can be confident that the molecule meets global standards. Also, we don't want to just do the development work in India for medications to be used in the US. We want to develop pharmaceuticals that are important for India.

Pulse: What are the new models you are seeing in the biotech space?

JN: The other partnerships that people are taking are what I call large "'bio buck'" deals that are full risk. They'll take an asset from Merck or Lilly, bring it in pre-clinical, develop it through phase 1, and get some

Continued on PAGE 39 >

RUNNING AN INNOVATIVE HOSPITAL: FROM BLOGS TO SUBMARINES

The hospital is one of the most complex businesses in the country. Everything from getting paid to delivering your core service is mediated through systems where the manager does not have direct control. While the final judgment for most businesses is profitability, hospitals combine an array of metrics from health outcomes to charity care to financial sustainability in order to define success. How does one lead a hospital in today's environment? What does the industry look like from this seat? The Pulse spoke with Paul F. Levy, President and CEO of Beth Israel Deaconess Medical Center, to get one executive's perspective.

BIDMC is a teaching hospital of Harvard Medical School. The patient care unit maintains approximately 621 licensed beds, with 800 full-time staff physicians and 1,100 full-time registered nurses. BIDMC consistently ranks among the top four recipients of biomedical research funding from the National Institutes of Health. Research funding totals nearly $200 million annually.

S. Regan Murphy
WG'10

The Pulse: You shared on your blog why you initially hesitated (and finally agreed) to purchase one of the latest technologies, a da Vinci Surgical System. How do you make these types of decisions and find the balance between adoption of innovation and evidence-based medicine?

Paul Levy: We are an academic medical center and sometimes even we do not know that innovation is going to be cost effective. We have many facets of clinical research occurring at BIDMC daily where we are trying things out, and that is part of our job. However, that is very distinct from buying a piece of equipment that has no documented clinical value, as is the case with this robotic surgery system. Intuitive Surgical has done a marvelous job at creating demand for this robot. Their sales force consists of the surgeons who bought it, who of course are going to say nice things about the system, and the men who have been operated on by it recently, who are also going to say good things about it. Then other men who have prostate issues and want the best possible outcome for their situation put pressure on their urologists to have this machine, threatening to go elsewhere for treatment [if they cannot get access here]. The other problem is that the firm has a monopoly so there has been no price reduction over time and, frankly, no technological enhancements to the machinery.

Pulse: What changes would you like to see made by payers to improve the health care system?

PL: The payers do not necessarily know how to improve the system. To give you an example here in Massachusetts, Blue Cross Blue Shield is very committed to what they call "transformational change of the healthcare industry." Their idea of how to rid our system of misuse, underuse, and overuse is to change their reimbursement model to a form of capitation with bonuses for meeting certain quality metrics. However, what they are asking us to do is to take on the insurance risk of our healthcare system. As a tertiary care institution, we would be reimbursed an annual sum for all care needs - from primary care to secondary to skilled nurse facility to nursing home. But there is an underlying question – how can I control the quality and cost of care at facilities that I do not even own? Their answer is that I can sign contracts with those other providers and somehow hold them accountable, but that may not be realistic.

The other problem with their plan is that the proposed metrics for quality – what we must keep track of in order to receive financial bonuses – may be the wrong ones. They are the traditional CMS quality metrics. We are working more broadly on trying to eliminate harm in the hospital. We also want to do the other stuff that makes sense, but to distract us managerially with keeping those metrics – to teach to the test rather than to pursue the overall goal – is the wrong approach. We are trying to make significant improvements in what we are doing, and it is not clear that we need a change in the reimbursement methodology to make that happen. As the old expression goes, "When you have a hammer, everything looks like a nail." Well, the only tool payers have is the reimbursement system, so that is what they are attempting to use.

PAUL F. LEVY
PRESIDENT AND CHIEF EXECUTIVE OFFICER OF BETH ISRAEL DEACONESS MEDICAL CENTER

Paul F. Levy was appointed President and Chief Executive Officer of the Beth Israel Deaconess Medical Center in Boston in January 2002. Previously, Mr. Levy was the Executive Dean for Administration at Harvard Medical School, an Adjunct Professor of Environmental Policy at MIT, Executive Director of the Massachusetts Water Resources Authority, Chairman of the Massachusetts Department of Public Utilities, and Director of the Arkansas Department of Energy. Mr. Levy is the author of numerous articles, the co-author of Negotiating Environmental Agreements, and blog author of "Running a Hospital." He serves as a member of the MIT Corporation and on the boards of ISO-New England, the Risk Management Foundation, and the Celebrity Series of Boston.

Pulse: Do you think the current policy environment is supporting or inhibiting progress and innovation in health care?

PL: CMS is looking at things such as never events* - they will ding you if someone comes back after surgery because that is the type of thing they measure. It looks to Congress like they are doing something. But in terms of really affecting change in the healthcare system, these are not the high priorities. Do they really think that we are trying to have never events? No. We're going to change the way we do business because we want to eliminate harm. And at that point, we will catch the never events as well. However, if the focus is on those discreet things then you miss the bigger story of how to change the provision of care for the better. [*Never events are defined by the Centers for Medicaid and Medicare Services (CMS) as serious and costly errors in the provision of health care services that should never happen.]

Pulse: You posted your salary online on your blog – Why did you decide to open up this conversation?

PL: Once a year the 990s are posted and the [Boston] Globe writes a story on the salaries*. I thought I should just write a piece on what my salary is, how it is calculated, and who determines it. That way people understand that it is the Board determining it and not me. Let's see what people think about it. [*990s refers to IRS Form 990 which is filed by non-profit organizations.]

Pulse: Would having every provider and all of their information be publicly available be a good thing for the healthcare system?

PL: Yes, and not for the reasons you might think. It would have very little to do with giving consumers information because there's no indication that consumers use any of that information to make decisions about which doctor they go to or which hospital. But it is important for doctors and nurses. Knowing that this information is out there will affect their behavior. It's a way of holding ourselves accountable. Because of pride and competitiveness, they will seek to do better. I do not need to use a relative benchmark. If my standard for central line infections is to have zero infections, then I don't care what the people across the street are doing. It is not a competition with them, and their numbers do not matter to me. So, this is very inwardly-focused. Isn't that ironic? By public disclosure, we get an internal focus.

Pulse: BIDMC has received much press for working towards quality improvement. In your opinion, what has been helpful to innovating in this area?

PL: Brent James mentioned during a visit that hospitals are the fourth largest health hazard in America. This is obviously not because people working in hospitals want to hurt patients, but because the system in which they operate tends to create too many opportunities for errors that result in harm. You cannot attack clinicians on the safety issue because there would be too much denial. Instead, what we try to do is teach people about process improvement in general. After two years, we unfortunately found that we are one of the national leaders in quality improvement and

Continued on PAGE 39 >

< PAGE 4 Microsoft and the Health Care Ecosystem...

common infrastructure so research can spend less time manipulating data and more time learning from it.

Pulse: If you had three wishes or goals that you would like to accomplish in your field – and unlimited resources – what would they be?

PN: One would be basic man-machine user interface that enables physicians and nurses to better adopt advances in technology. One of the barriers to EMR adoption is that it slows clinicians down; the user interface is not flexible enough. Also, clinicians have their own set of shortcuts that they use to memorize set steps that they take. If we can change the man-machine interface in a way that speech recognition really works or that sheer presence logs me into the system in a way that is relevant to me, this might address some of their chief complaints.

Another would be to imagine more flexible surfaces that are better at displaying complex models or images, such as a gesture-based interface in an operating environment. There is an imaginable set of things that we could do to improve technology adoption that would allow health care professionals to perform better in their work.

My focus for the last few months has been on health reform. Frequently the debate veers quickly into tactics, and I think that folks such as you could step back and think about the real objectives and driving principles around which we could have a reasonable debate. If we expect the ecosystem to get healthier, everyone needs to have an internal dialogue and peer groups need to educate each other on the goals and underlying principles against which we can make a case. I encourage you and your conference participants to focus on this dialogue.

< PAGE 16 Wanted: New Molecules—How Large Pharma Sources Innovation...

YG: We are making a real effort to ensure that we're able to capture some of the opportunities that are presenting themselves in emerging markets. In particular, GSK has a really good foothold in many of these markets already, particularly India. A key aspect of our strategy will be creative deals like the one we did with a South African company called Aspen. With that deal we are essentially paying as we go to access the emerging market portfolio. Overall, the deal encompasses something like 450 molecules and 1,200 products, which we can buy into as required. We've also set up a drug discovery unit in China focused on neurosciences, and we will continue to consider how we can shape our existing portfolio to meet the needs of folks in emerging markets.

< PAGE 27 Shifting Ground: New Rules for Medical Technology Transfer...

What we're really saying is that this is the role of the FDA for the riskiest and most closely reviewed products. When the FDA approves a PMA, and the Riegel decision only relates to rigorously prepared PMAs, what the FDA is doing is looking at all the evidence, looking at the balance of safety and public health. They are making a determination that even though there are some risks with a given device, that overall public health is improved by having access to that device along with knowledge of its risks.

Now if you allow for the Riegel decision to be overturned, what that is really saying is that the FDA's judgment on that matter is not supreme, and that local juries should be able to override it by reviewing failed cases to court. In these instances, the local jury only hears the story, told by a litigator, of the one person who failed to respond even if the patient was subjected to off label use or other issues unrelated to the device. The jury hears that and is likely to sympathize, perhaps concluding the device should not be available, or this device has to be altered to prevent an isolated event from recurring. The jury's ruling actually becomes part of state law, and absent federal preemption, such state law would prevail. That would force random jury verdicts heard at the state level to be imposed upon a device manufacturer and manifest in changes to their device or changes to their labeling. This would lead to devices sold one way in Oklahoma and another way in Nevada and a third way in Minnesota. Those sorts of changes would bring chaos to the marketplace such that the physician would not really know exactly how he is supposed to practice with a given technology.

< PAGE 33 Using Technology to Drive Access In Rural India...

Pulse: Who do you see as your major competitors?

OI: I think there are relatively few multinational companies who can do what we are doing. There are many local companies in India, but their access to technology and ability to implement is limited. There are many more people in this sphere outside India focusing on local delivery. In China there are thousands developing delivery systems, and they will be real competitors. This presents us with the challenge to be local and to use our abilities to maintain a competitive advantage.

< PAGE 35 Building a Global Model for Drug Discovery...

milestones. But they only get a big payout if it gets through phase 2 successfully, and the large company will buy it back.
It is a risky model, and I think that model is getting harder and harder to finance even in India. I think the collaborator model with shared risk is going to be more robust over time and be able to sustain shocks in the system of the sort that are going on right now.

Pulse: How is the pharmaceutical industry changing?

JN: We'll see continued consolidation in the pharmaceutical business. We will wind up globally with no more than five to ten companies that will be able to market and do everything in that space
Innovation will happen on a smaller scale. A good model will be to look at how things have happened with computers. A few big companies have a special focus in their technology and approach. And then you have the assemblers who go around the world, doing hundreds of collaborations, trying to get the best technology, pull them together and provide a quality product for the consumer.

This is the same radical transformation that is happening in the pharmaceutical industry. The days of the Fully-Integrated Pharmaceutical Company (FIPCO) are over. It is as over as when Henry Ford said I make a lot of windshields, so I need to have a glass plant. Too much

< PAGE 37 Running an Innovative Hospital: From Blogs to Submarines...

safety. It is dismaying because we were hoping to learn significantly from other organizations that had already done this. Instead, we find people calling us to learn how to do it.

Pulse: Besides Toyota, is there a group outside of healthcare whom you have been able to learn from as quality innovators?

PL: Alcoa under Paul O'Neill, and the nuclear submarine corps of the U.S. Navy. The first nuclear submarine was produced early in the 1950s and they have never had an accident. That is a pretty exemplary track record, and it is because everybody onboard understands that their job is to point out any potential problem. When people see an issue, they work together to study the root cause and solve it. Finally, whatever issue is identified is shared with other crews. So it is a constant process and a constant discovery in how to improve the submarine system. Everyone has a guiding role to play, and this cuts through the most hierarchical field - the military.

Pulse: What potential is there for providers to work with private industry to improve care cost, efficiency, and quality?

PL: There should be a lot, but I think it's fair to say that people from other industries that come into healthcare thinking that they can quickly apply something from outside find that they quickly hit a brick wall. The culture of hospitals is important, and it is crucial to consider as you approach making successful change. Now, an interesting way for people from private industry to get involved is by serving on the board of trustees over a hospital and bringing their perspectives and wisdom from other fields to board-level discussions. However, I think some improvement is going to have to be invented in-house, and perhaps that will be a slower process.

ALL STAFF MEMBERS ARE WHARTON MBA STUDENTS WITHIN THE HEALTH CARE MANAGEMENT MAJOR.

Jill A. Schondebare, WG '09
Managing Editor

Jill is an MD/MBA candidate, currently in her second year at Wharton. She graduated magna cum laude from Cornell University in 2001 and has a professional background in management consulting at Aon Corporation. After Wharton, Jill will return to the University of Connecticut Medical School to complete her MD degree. She plans to pursue a career as a practicing physician and business leader in the global health industry.

Jonathan Maack, WG '09
Managing Editor

Jonathan is an MBA candidate, currently in his second year at Wharton. He graduated summa cum laude from New York University and has worked in international development at The World Bank Group and in hospital and health system consulting at The Advisory Board Company. After Wharton, Jonathan will be joining Bain & Company's New York office, where he will focus on private equity, healthcare and restructuring engagements.

ACKNOWLEDGEMENTS

The Pulse would like to thank our interviewees for generously donating their time and insight. We would also like to thank June Kinney and the Wharton Health Care Business Conference organizers for their support and Kim Pesch and the team at MOD Worldwide for the look and feel of the publication.

Finally, *The Pulse* would like to make special note of our sponsors at Oliver Wyman, who contributed both valuable content and financial resources to make this publication possible.

THE PULSE EDITORS

Emily Cooper, WG '10
Emily is an MD/MBA candidate, currently in her first year at Wharton. She graduated summa cum laude with a BA in Neuroscience from Hamilton College and completed her first three years of medical school here at the University of Pennsylvania. Emily founded a resource website for medical students and currently writes a monthly column for Medscape, a division of WebMD. She plans to pursue a career that allows her to combine her clinical and business knowledge to improve care delivery and health care business models.

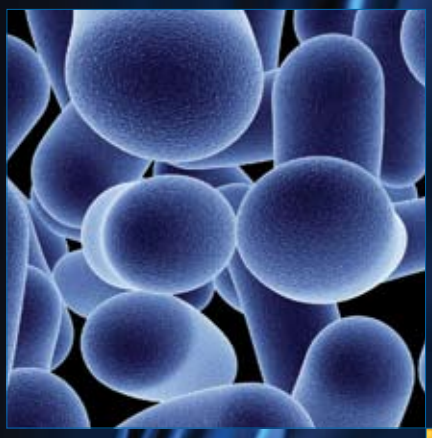
S. Regan Murphy, WG '10
Regan is a first year MBA candidate. She graduated with an A.B. in Biology Modified (Neuroscience) from Dartmouth College in 2002. Regan's professional background includes management consulting with Deloitte Consulting LLC, advocacy consulting for Genentech and the Pfizer Foundation, and being part of The Advisory Board Company's initial business intelligence team. After Wharton, Regan plans to pursue a career as a business leader in innovative health solutions.

Neil Parikh, WG '10
Neil is an MD/MBA candidate, currently in his first year at Wharton. He is studying medicine at the Keck School of Medicine at the University of Southern California. In additional to his clinical work, Neil has a background in medical journalism having worked for the CNN medical unit and the American Medical Association's ethics journal. He is looking to pursue a career in health care systems, particularly focusing on developing better access through technology.

Marina Tarasova, WG '10
Marina is a first year MBA candidate with a double major in Health Care and Strategic Management. She graduated with honors from the University of Illinois at Urbana-Champaign with a major in Business Administration and Management Information Systems. Prior to Wharton, Marina completed the Information Technology Professional Development Program at Abbott after which she transitioned to a sales role within Abbott's Primary Care and Immunology Divisions. After graduation, Marina plans to pursue a career in management consulting.

Allison Walsh, WG '10
Allison is an MD/MBA candidate, currently in her first year at Wharton. She graduated summa cum laude from Washington University in St. Louis in 2005 and has spent the past three years attending medical school here at the University of Pennsylvania. After Wharton, Allison plans to complete a residency in Obstetrics and Gynecology. Eventually, she hopes to work on the business aspects of healthcare policy and administration.

Richard William Whelton, WG '10
Richard is a second year MBA candidate. He graduated from the University of Oxford in 2004 with a degree in Molecular and Cellular Biochemistry. Prior to Wharton, Richard worked at Cancer Research UK in London as a Strategy Unit Project Manager. He plans to pursue a career in health care consulting.

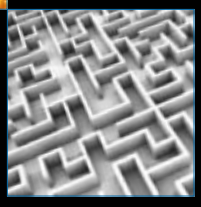


Business Development and Licensing

Sales and Marketing

Clinical Development

Operation and Supply Management



Post Merger Integration

Strategy and Business Transformation

OLIVER WYMAN

Oliver Wyman's Health and Life Sciences practice advises leading health and life science companies, including pharmaceuticals, biotech, and medical devices, as well as payers, health care services, and providers on a range of strategic and operational issues. Oliver Wyman clients appreciate that we go beyond recommendations to accelerate execution. And they look to us to have a major impact on both their top and bottom lines.

Learn more about us at **www.oliverwyman.com**

Atlanta ▪ Barcelona ▪ Beijing ▪ Boston ▪ Calgary ▪ Chicago ▪ Cleveland ▪ Columbus ▪ Dallas ▪ Detroit ▪ Dubai ▪ Düsseldorf ▪ Frankfurt ▪ Hamburg ▪ Hong Kong ▪ Houston ▪ Istanbul Leatherhead ▪ Lisbon ▪ London ▪ Los Angeles ▪ Madrid ▪ Melville ▪ Mexico City ▪ Milan ▪ Milwaukee ▪ Montréal ▪ Munich ▪ New Delhi ▪ New York ▪ Paris ▪ Philadelphia ▪ Pittsburgh Portland ▪ Princeton ▪ Reston ▪ San Francisco ▪ São Paulo ▪ Seoul ▪ Shanghai ▪ Singapore ▪ Stockholm ▪ Sydney ▪ Toronto ▪ Tokyo ▪ Washington, D.C. ▪ Zurich