

WHLE

SPRING 2007

A publication by the students
of The Wharton School,
University of Pennsylvania
NOT FOR SALE

THE WHARTON HEALTH CARE LEADERSHIP EXCHANGE

RISE OF THE MARKET

How the Informed Shopper Is Changing Health Care



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Regina Herzlinger
Uwe Reinhardt
and
BroadReach Healthcare
Revolution Health

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FROM THE EDITORS

As the Wharton Health Care Leadership Exchange (WHLE) enters its 3rd year, we decided to revisit the mission of this publication. As the title suggests, our mission is to “create a forum, in print, for the exchange of ideas on the most challenging and topical issues in the health care industry today, and to share that exchange with both attendees of the Wharton Health Care Business Conference, as well as others who could not attend the event.” In September 2006, we asked ourselves the following: Are the topics we address in the WHLE representative of the important questions that face our readers? Do our leadership interviews offer practical knowledge and insight in a way that may not be achieved through our Conference or other professional forums?

This year, we celebrate the 12th year of the Wharton Health Care Business Conference entitled *Convergence: From Yesterday's Boundaries Emerge Today's Possibilities*. Conference keynotes, panelists and participants represent each of the major health care sectors, and include dynamic leaders from life sciences, health care delivery, finance and entrepreneurship. In order to provide in-depth discussion and learning for participants, the Conference does not and cannot possibly address all emerging trends in the health care market. Therefore, we decided to focus this year's WHLE on areas that are critical to the health care industry, but are outside of the scope of this year's Conference.

Our feature section (*Rise of the Market: How the Informed Shopper is Changing Health Care*) captures what we believe to be an exciting trend that has the potential to radically change health care delivery. From the emergence of retail clinics and medical tourism to information availability, we explore how market forces continue to shape payer and provider models. We develop this framework further as it applies to health care policy (*Understanding the Politics of Science in America*) and global health (*Unique Partnerships to Conquer AIDS in Africa*). Here, we consider the broader impact of market-driven health care, including the losers from the US consumer-health movement, challenges of bringing drugs like Plan B to market, and creative ways to connect people and private services to global health needs. For the first time, we have supplemented our tradition Q&A leadership interviews with two WHLE Editorials, which allows students to share their unique perspectives.

The WHLE brings together the voices of industry leaders, academics, and students who share a passion for health care. We hope that this year's WHLE facilitated the exchange of ideas and contributed to the advancement of health care knowledge for our readers.

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Central to the Wharton Health Care Management student experience is each individual's ability to shape and participate in a number of dynamic student-run initiatives. We highlighted some of these milestones below. For more information about the Program and its student-run initiatives, please contact June Kinney (kinneyj@wharton.upenn.edu).

Wharton Health Care Management Program: The Wharton team finished 2nd place at the Kellogg Biotechnology Case Competition held on January 19, 2007. The team (WG'08ers Eugene An, Keely Beck, Scott Freishtat, and Josephine Harada) presented their recommendations regarding investing in a placebo-controlled clinical trial of a innovative Parkinson disease therapy to a panel of judges composed of Genzyme executives and Kellogg professors.

Wharton Health Care Club: In January 2007 the Wharton Health Care Club formally launched a new initiative, the Health Care Board Fellows Program. The program serves to meet the needs of Health Care Management MBA candidates who are both personally and/or professionally interested in health care social sector leadership. Program participants will gain firsthand experience as Board Observers on the boards of socially responsible non-profit organizations dedicated to health care pursuits.

(<http://clubs.wharton.upenn.edu/whcc/>)

Wharton Health Care International Volunteer Project (WHIVP): The WHIVP is designed to give Wharton Health Care Management students the opportunity to participate in service projects for health care systems with limited resources and severe health problems. This year, WHIVP conducted six projects, with five taking place in Sub-Saharan Africa and one in India. WHIVP further developed a partnership with Aravind Eye Hospitals in Tamil Nadu, India, and also introduced a new partnership with Doctors of the World through a microfinance project in Kenya, with the hopes of establishing a steady pipeline of projects for future years.

Wharton Health Care Business Conference (WHCBC): The WHCBC, which was held February 15th and 16th in downtown Philadelphia, celebrated its 12th year by exploring the theme of *Convergence: From Yesterday's Boundaries Emerge Today's Possibilities*. As the leading health care business forum for industry professionals, academics, and students, the Conference is at the forefront of industry thought leadership. The two-day annual event draws over 500 attendees including students, professionals, and academics from across the nation. (www.whcbc.org)

Penn Biotech Group (PBG): The PBG is a cross-disciplinary club that promotes education and awareness within biotechnology, including science, business, law, and medicine. The PBG completed 15 consulting projects with local life science companies and also initiated the PBG Entrepreneurship Program, which assists graduate business and science students in starting companies. (www.pennbiotechgroup.com)



HEALTH CARE POLICY

Understanding the Politics of Science in America

With the recent election of a Democratic Congress, many believe that a new era of health care reform is being ushered in. We asked three leaders from diverse backgrounds – political, legal, and academic – to evaluate the current health policy situation and to give us their vision of what the future holds. Former Speaker of the House and founder of the Center for Health Transformation **NEWT GINGRICH** shares his views on some of the major issues affecting health care today, and advocates the cooperation of both political parties to effect change in the future. Health care economist and Princeton University professor **UWE REINHARDT** evaluates potential solutions for the health care delivery system and reflects on the current political environment. **PETER BARTON HUTT**, former legal counsel of the FDA, then examines a particular case of controversy: the debate surrounding the over-the-counter approval of Barr Labs' Plan B.

Lessons from 2006 and Hopes For 2008



Since retiring from Congress, NEWT GINGRICH has worked extensively on the issues of health and health care, devoting the majority of his time to advocating a transformation of the entire system. In 2003, he founded The Center for Health Transformation (www.healthtransformation.net), a collaboration of public and private sector leaders dedicated to the creation of a 21st Century Intelligent Health System that saves lives and saves money.

During his twenty years in Congress, Speaker Gingrich was committed to improving America's health care system, co-chairing the Republican Task Force on Health for four years prior to becoming Speaker. Under his leadership as Speaker, Medicare was improved, investment in medical research was dramatically increased, and FDA reform was enacted to allow for quicker approval and access to new medicines for those with terminal and degenerative illnesses.

Mr. Gingrich is currently a member of the Advisory Board for the Agency for Healthcare Quality and Research and sits on the Board of Regents at the National Library of Medicine. In addition, he co-chairs the National Commission for Quality Long Term Care. He has received numerous health and health care honors and awards, including the 2005 HIMSS Advocacy Award for his leadership advancing information and management systems for the betterment of human health.

Speaker Gingrich has authored numerous health publications, columns and books, including *Saving Lives and Saving Money*, which describes the vision and principles of the Center for Health Transformation. His latest best-seller, *Winning the Future*, includes key chapters on health and health care, based on his work at the Center. Most recently, Speaker Gingrich and CHT CEO and President Nancy Desmond published a new book, *The Art of Transformation*.

Here, Mr. Gingrich shares his views on the major issues affecting the US health care system today.

PART I: PLAN B, STEM CELLS AND THE FDA REGULATORY PROCESS

WHLE: Some observers have commented that the FDA has received criticism from the scientific research community because it is increasingly influenced by politics. An example of this criticism comes from the debate surrounding Plan B. Republican Senator Tom Coburn said the following in *The Washington Post*: "This decision [to approve Plan B] has nothing to do with science or FDA rules but has everything to do with politics." Even though liberals contend that politics in fact delayed Plan B's approval, both sides seem to agree that politics played a significant role in this situation. How effectively has the FDA

balanced scientific rigor and political interests?

NG: First of all, the FDA is always under some level of political scrutiny because it's a government agency, and on some issues like this particular pill, you're dealing with ideological issues, but other times you're seeing the agency is influenced by the quantity of newspaper coverage and whether or not a topic is a hot topic. So I think that there's no question that they accelerated approval of HIV medication as a direct function of political pressure. I think some of that's actually fairly healthy. The ideological arguments are probably unavoidable because they're part of how the country talks to itself when you get into health issues that also involve ethics and values. Democracies ought to have some substantial

scrutiny. The question is whether they're actually making decisions that are purely political. If they were to put something on the market that was unsafe for political reasons, that would be bad. I have no evidence that they've done that.

WHLE: You've mentioned that ideological arguments have always been part of the debate – that's fair – but do you observe an uptick in these types of arguments within the context of the FDA?

NG: No, they're very focused on issues that are specifically related to things like abortion, which has been a political issue in this country for over thirty years. But when you look at the 95% -98% of what the FDA does, it has remarkably little political pressure, and, if anything, is somewhat too bureaucratic and somewhat too isolated.

WHLE: Stem cell research is another topic that has seen heated debate, both nationally in regards to federal funding, and also at the state level, most recently during midterm elections. Advocates of stem cell research argue that it could lead us to cure currently untreatable diseases, and could also redefine the future of medical therapies. Are we running the risk of stifling scientific research in the US, or worse sending it overseas, due to some of the political gridlock around issues such as stem cell research?

NG: Well, to the best of my knowledge, no proposal has been introduced that stops stem cell research in the US. Harvard was doing it with private money; Wisconsin was doing it with state money; New Jersey's doing it with state money; California was doing it with state money. My hunch is that there's more stem cell research underway in the US than anyplace else in the world. The argument was over whether or not the federal government should finance research of stem cells outside of a narrow number of lines, and I frankly thought that the President probably

drew the line in a way that didn't make a great deal of sense.

I favor stem cell research as long as it does not involve the product of an abortion, but I am opposed to starting down a road where there are incentives for abortions to occur for research purposes. There's very high likelihood that we will presently be getting stem cells at the 16th or 32nd multiplication of the initial cells and that they will actually be withdrawn with no harm to

the embryo and that probably a generation from now, everybody will have their own stem cell deposit that's theirs personally, that allows them to then re-grow various organs if they need to.

WHLE: How do you think politicization of the FDA will play out in the future, in terms of financing, leadership or any other structural changes?

NG: At the Center for Health Transformation, we strongly favor rethinking some of the FDA's rules of engagement, particularly in the brain sciences. And we favor more than adequate funding for FDA. I mean, it makes no sense to spend thirty billion dollars a year at NIH on research and then have a bureaucratic bottleneck that stops the thing that could save your life from getting to market. I strongly hope the new Congress will take a serious look at reviewing FDA to see how we can make it more effective and more aggressive in helping move breakthroughs to market, so that people can actually get access to the new opportunities and better care.

WHLE: You mentioned some of the burdens of FDA regulation, and the drug and medical device regulatory process has also been criticized by the industry as too onerous, yet too hasty by some safety critics, who reference Vioxx and drug-eluting stents. With the urgency to bring new technologies and therapies rapidly to market, what, if anything, does the FDA need to do to remain an agile yet

"[M]y hope is that the President will focus on preventive care, on wellness, that he will focus on health information technology. I mean, if Hillary Clinton and Patrick Kennedy and I can agree, there ought to be some way for the President to reach out and agree with some of these folks."

prudent regulatory body?

NG: First of all, I think you always have to weigh lifesaving versus non-lifesaving. For example, if you found a potential breakthrough in Lou Gehrig's disease, because it is so aggressive and so fatal, you would want to take fairly high risks in allowing the experiments, because people are going to die anyway and they're going to die very fast, and it's a very difficult disease. So I think the FDA has to have different sets of rules depending on what it's dealing with.

Second, one of the most powerful arguments for going to electronic health records is that it enables you to keep track in real time of any side effects. [Currently], there's no access. Kaiser Permanente was one of the first places to surface Vioxx because they have an electronic data flow that allows them to suddenly notice anomalies and check to see whether there are patterns. And as we get to better and better interaction between electronic health records and mass-quantified research data on a de-personalized basis, you will actually be able to be more risk-taking in approval because you'll know in real time when you have a problem and you'll be able to adjust and rethink it if it turns out to be a problem. Electronic health records are going to have a very, very positive kind of approach, I think, to the FDA situation.

One of the things we're going to be proposing at the Center is the creation of a "national institute of health" specifically for using large quantitative electronic data to develop the kind of capabilities that would give you access to negative results, or by the way, effective use of off-label which turns out to be usable enough that maybe the FDA should be voluntarily migrating things on-label if they work.

“Think of Ray Crock and think of Sam Walton and ask yourself how you could do that in the providing of services and products in health care – because the faster we create a genuine consumer market of smart entrepreneurs offering better outcomes, better services and better products at lower costs, the more rapidly we’re going to migrate to a 21st century intelligent health system.”

PART II: STATE AND FEDERAL GOVERNMENT REFORM INITIATIVES

WHLE: You've mentioned electronic medical records. Thus far, what have been some of the big wins on the health IT front?

NG: Well, I think first of all, you have to say that the Veteran's Administration was an extraordinary achievement and that they deserve a lot of credit for being real pioneers. You'd have to include Kaiser Permanente, the Mayo Clinic, the

Inland Northwest Health Services in Spokane, Washington, Peacehealth in Oregon, and the use of new metrics at Piedmont Hospital in Atlanta. There are lots of places where you see breakthroughs underway. But I'll tell you a story that I think is just fascinating. Allscripts took me to Alpharetta, GA to interview the doctors who run the North Fulton Family Medicine Clinic. In 1998, they went to an ambulatory care workflow organized electronic health record designed to make their lives easier. The very first year, they saved an average of \$33 per patient visit – a million dollars, in

a four-doctor practice. They are today, eight years later, a ten-doctor practice, they are totally paperless, and yet it is hard to convince other doctors that going to an electronic health record doesn't cost you money – it makes you money. These guys are dividing up several hundred thousand dollars a year in savings, and as one of them said to me, they now go home at 5:15pm, having done all their paperwork as a normal part of getting through the system – just an amazing difference from what people are used to.

WHLE: You mentioned a several different examples, a lot of organic examples from different states. Are we missing something in terms of a big push nationally to try to coordinate this?

NG: Yeah, I think we are. I've advocated since we first wrote, and I should cite the book – we wrote a book called *Saving Lives and Saving Money* which was first drafted in the fall of 2002, and then we have a new book that just came out [in late November 2006] called *The Art of Transformation*, which Nancy Desmond, the CEO of the Center for Health Transformation co-authored with me. *The Art of Transformation* really is a basic introductory book about how to effectively transform institutions, and it's based on what is now over forty years of work we've done on large scale change.

You go back and look at *Saving Lives and Saving Money*, as early as 2002, I began to advocate that we ought to have the equivalent of Eisenhower's 1955 interstate highway system. Eisenhower originally proposed the National Defense Interstate Highway Act, and its point was that if you had a nuclear war, you needed the capability to evacuate cities. Now, we didn't just build these and put it off to one side under lock and key. They became the base of all middle class travel in America, and they became the base of the entire modern trucking industry and the rise of things like UPS and FedEx. So, in that context, I've argued that we ought to have a National Defense of Electronic Health Information and Technology, because in Katrina, we had millions of paper records destroyed. Nobody has been wanting to quantify for us the cost of those paper records. The federal government had to pay a ton of money to have people go back out and redo your labs, redo your x-rays.

Imagine you're halfway through chemotherapy with cancer and you've suddenly lost your records. We think that if you're faced with the possibility of an engineered biologic attack, a pandemic, or a nuclear event, that building a nationwide electronic health record capability is something the federal government should finance. We haven't won that argument, but I still think it's true, and I think it will cost us lives to continue to have a paper-based system.

WHLE: Shifting gears a little bit, what is your evaluation of the Massachusetts health plan?

NG: I think that the jury's out. I think that it was a very serious intellectual effort. I very much

like what Governor Romney tried to do. I think that the State Legislature up there is so liberal that they may have made it unworkable. I think we don't know yet, but there's some evidence that it may come back as so expensive that it is not sustainable. That would be unfortunate, but it's possible. We at the Center believe that our goal should be 100% insurance coverage so that every American is part of the system.

WHLE: Do you see any other examples of innovative state initiatives that you think should be modeled in other states?

NG: Well I think [the Massachusetts health plan] comes the closest. I think President Bush was on the right track but didn't pursue it. It seems to me that if you "voucherize" Medicaid so that everybody could buy into the insurance pool, you then have a tax credit so that people could gradually migrate up. You'd start with the voucher at the very bottom, go through a tax credit on the way up, then get to a regular tax deduction. Combine that with the ability to have an association plan so nobody ever bought individual insurance, they individually bought into pools that were grouped to lower the total risk cost, probably combine that with some kind of reinsurance mechanism, to create a 300 million person reinsurance pool for the whole system. And finally, design the whole thing so that you'd also say that everybody above a certain income has to have insurance. The fastest growing group of the uninsured are people who are able to buy insurance, usually young males, who make a decision that they'd rather buy a beach house, or they'd rather buy a better car, or they'd rather go on vacation.

Part III: Bipartisan Compromise, the 2008 Election and Beyond

WHLE: Focusing again on the national level, many observers believe that the newly-elected Democratic Congress will have health care issues prominently featured on its agenda. What do you think will be the major health care initiatives on the Democratic agenda moving forward?

NG: Well, I think that it depends on what they want to do. If they just want to pick a fight with the administration, they'll focus on negotiation with pharmaceuticals, or something designed

to get into a brawl with Bush in order to set the stage for 2008. I think if they want to look at what's working in America, if they want to look at the impact of the \$4 a month generic drugs from Walmart, and the free child antibiotics from Meijers, and the rise of the minute clinic as a dramatically less expensive intermediary than emergency rooms – there are a lot of good things happening that could lead to a much more creative two years than people expect.

WHLE: After midterm elections, the press has repeatedly referred to your ability as Speaker of the House to reach middle ground within Congress and with the Executive Office. What is your advice to the current Congress and President to seek compromise and to advance a health care agenda that both sides can agree on?

NG: Well, my hope is that the President will focus on preventive care, on wellness, that he will focus on health information technology. I mean, if Hillary Clinton and Patrick Kennedy and I can agree, there ought to be some way for the President to reach out and agree with some of these folks.

WHLE: From your perspective, what will be the key health care issues on the agenda for the 2008 elections? What are the major problems each presidential candidate will have to address as part of their campaign?

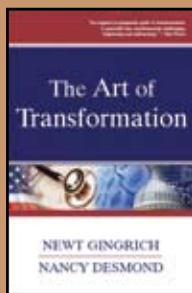
NG: Well, I think finding a way to get to universal coverage or health insurance is important. I think finding a way to get to transparency in cost and quality so people can make informed choices is very important. We're going to be proposing the development of a national Medicare market, where seniors can go online and find out the cost of services and goods. Go to www.myfloridarx.com, and to www.floridacomparecare.gov – these are two sites Jeb Bush has put up.

The first one, www.myfloridarx.com, you can put in any of the hundred most frequently purchased drugs in Florida, your zip code in Florida or a city in Florida, and every drug store comes up, starting with the least expensive, going to the most expensive. When it was first set up, there was a 300% price differential in Ft. Lauderdale, and a 600% differential in Miami

Dade County. The second site's even bolder – it's www.floridacomparecare.gov – it puts every hospital, every procedure, the number of times a year the procedure is done, the quality of the outcome, and the price. And those are the beginnings – I think creating a national Medicare market of real information about price and quality and being willing to pay the travel differential if seniors are willing to go to equally qualified but less expensive places would do more to bring Medicare costs under control than any other single thing you could do.

WHLE: Last question for you. At Wharton we have a lot of entrepreneurs and we will graduate a lot of people interested in entrepreneurship. What are some of your suggestions to future business leaders going out to try and influence health care?

NG: Well my first suggestion is read Drucker's *Effective Executive*, which is the best single book I've ever read in how to be effective. Buy the paperback, read it once and underline it, and keep re-reading it until you have it thoroughly understood. My second suggestion is to find an area where there is a consumer value that the consumer will understand and pay for – because if they won't understand it and pay for it, it doesn't exist. Think of Ray Crock and think of Sam Walton and ask yourself how you could do that in the providing of services and products in health care – because the faster we create a genuine consumer market of smart entrepreneurs offering better outcomes, better services and better products at lower costs, the more rapidly we're going to migrate to a 21st century intelligent health system.



Announcing Newt Gingrich's new book, *The Art of Transformation*, now available online. The book is "an introductory book on how to effectively transform institutions" and is co-authored by Nancy Desmond, the CEO of the Center for Health Transformation.

Consumer-Driven Health Care: Not Everyone Is Buying It



UWE E. REINHARDT, a native of Germany, has taught at Princeton University since 1968, rising through the ranks from assistant professor of economics to his current position. He has taught courses in both micro- and macro-economic theory and policy, accounting for commercial, private non-profit and governmental enterprises, financial management for commercial and non-profit enterprises, and health economics and policy. In 2002, readers of *Modern Healthcare*, a widely read American trade journal devoted to health care, voted him among the top 10 most influential personality in American health policy.

Professor Reinhardt has served on a number of government committees and commissions, among them the National Council on Health Care Technology of the then U.S. Department of Health and Welfare (1979-82) and the Special Medical Advisory Group of the then Veterans Administration (1981-85). Professor Reinhardt currently is a member of the Council on the Economic Impact of Health Reform, a privately funded group of health experts established to track the economic impact of the current revolution in health care delivery and cost control. He is also on the Board of Advisors of the National Institute of Health-Care Management, a Washington-based think tank devoted to issues in managed care. Professor Reinhardt has been or is

a member of numerous editorial boards, among them the *Journal of Health Economics*, the *Milbank Memorial Bank Quarterly*, *Health Affairs*, *The New England Journal of Medicine* and *The Journal of the American Medical Association*. Here, Professor Reinhardt evaluates potential solutions for the health care delivery system and reflects on the current political environment.

WHLE: Many groups are promoting different visions of the ideal state for health care delivery. Which ideas do you think best represent a viable solution for the delivery system?

UR: There are many viable solutions for the system but they reflect different ideologies. There are people who believe that health care is a social good that should be available to anyone regardless of socio-economic status on roughly the same terms. A viable solution would be Medicare for all, which is like the Canadian system, or any other kind of arrangement such as the Clinton Plan. Liberals tend to favor this approach. Political conservatives tend to believe that health care is really no different from food and should in fact be rationed substantially by income class. Those people would favor health savings accounts

(HSAs) into which families can make tax-deductible deposits, coupled with very high-deductible insurance policies. It would be viable, of course, but it would put the burden of health care self-rationing through the price system mainly on the lower half of the income distribution. And on top of that, because marginal tax rates are progressive, the tax preference for HSAs would make health care cheaper for rich people than poor people. Our perennial fight over universal coverage is really a battle between these two ethical doctrines. It is an ideological battle, not one over economics. After all, the annual cost of moving to full universal health insurance (at most between \$80 to \$100 billion) is much less than the annual cost of our venture in Iraq. As a nation, we could easily afford it.

WHLE: What are the key challenges that

we need to overcome to try to figure out what the “ideal health care delivery model” would be?

UR: The real challenge is that in America, everyone has their preferred vision for health care which is essentially driven by ideology and economic self interest. Everyone’s plan B, their second-best fall back option, if they can’t get their own plan, is the status quo. We call it Altman’s Law, after our colleague Stuart Altman. And that’s been so for over 50 years.

WHLE: You wrote a recent article for *Health Affairs* about Michael Porter and Elizabeth Olmstead Teisberg’s new book, *Redefining Health Care*. In the article, you argue that the real world of health care is much more complex than the authors contend. Can you talk a bit more about this?

UR: Their vision is good but it’s utopian. It’s the idea that you can carve up health care into distinct conditions around which doctors, hospitals, or clinics will then array themselves. The idea is that they would manage this jointly, and that they would quote one price for this, and somehow divvy up the income among themselves. The idea is that there would be reliable information on the quality of their work, and with that information, that these delivery arrangements with a free consumer-driven market would lead you automatically to the best consumer-friendly, high-quality health system. The problem is that health care cannot easily be carved up that way, that physicians in particular would not be willing to subject their own autonomy to groups like that. I mean, how would you figure out the alloca-

tion of income? In fact, these groups might be very unstable because they would be formed in an almost ad-hoc manner. So if you look at the obstacles, the quality ratings they’re after are very difficult to get. They can be unreliable if they’re self-reported – what would stop these people from lying? All told, it’s a great vision, which at the margin, for some conditions, you could do. You could have people do it for normal deliveries, or for standard heart surgery, but for the bulk of health spending, I don’t think that model really applies.

WHLE: Consumer-driven health care has been hailed by some as a revolutionary new way to contain health care costs in the US, and by others as a system that will place an undue burden of some patient groups. What are your views on these plans, and what do you think the future holds?

UR: First of all, to have consumer-driven health care, which truly puts patients into the driver’s seat, the absolutely fundamental prerequisite for that would be the existence of consumer-friendly, highly reliable information on the cost and quality of the health care delivered by individual doctors and hospitals. That does not now exist, except for little bits and pieces of it exist here and there. If you actually consult the

existing websites, they’re very sparse. Try it in Philadelphia today. Try to find a website that gives you the prices charged by gastroenterologists in the area, and information on the quality of their services. Go ahead, try it! Until you have websites with reliable information for the broad spectrum of health care, for all providers, to talk about consumer-driven health care is premature and, in fact, mischievously deceptive.

"[T]o have consumer-driven health care, it is essential for prospective patients to have consumer-friendly, highly reliable information on the cost and quality of the health care delivered by individual doctors and hospitals. That does not now exist in the U.S. with very few highly localized exceptions. Until you have ...such reliable information for the broad spectrum of health care, for all providers, to talk about consumer-driven health care is both premature and mischievously deceptive."

There are, however, people who say, “If you just force people to have \$4000 deductibles, then they’ll spend their own money and they’ll be more careful shopping around.” Shopping around how? “Shopping around” in health care today is still like going Christmas shopping with a blindfold on. God knows what you would buy for Christmas for everyone! I have observed that, in health care, our brave words always jump way ahead of our deeds. People talk about consumer-directed health care as if health care were like ordering restaurant food or buying cars. The truth is that we’re not even vaguely near being ready for that. The same, by the way, was true for managed care. In the 1990s, we said “everyone’s in managed care.” No we weren’t – everyone was in managed price discounts, not managed care. No one really managed care, no one did disease management, but everyone was in “managed care.” By the way, there’s always been a high incidence of felicitous delusion on America’s health care speaking circuit, including the much mouthed mantra that we still believe to have the best health system in the world. At its best the system does have no rivals but, as an emerging research literature shows, on average we don’t rank all that highly.

WHLE: If consumerism is not the long-awaited solution that many people had hoped it would be, what player in health care will drive the change?

UR: I personally think the old-style managed care along the Kaiser model with really well-managed HMOs is what ultimately an exhausted American people will tumble towards. Managed care as it should have been, and as it is increasingly practiced by some like the Kaiser health plan – prepaid, integrated group practices that can take responsibility for the whole patient. But you know Churchill’s dictum: in the long run, Americans will always do the right thing, after exploring all other alternatives. And we haven’t explored yet all other ridiculous alternatives. So we have some years to go.

WHLE: Critics of consumer-driven health plans (CDHPs) have argued that they will place an undue burden on lower income patients, and you’ve mentioned this also. To what extent do you think something can be done to improve the situation?

UR: You could do a number of things. First of all, if you want consumer-driven health care, you have to have the information infrastructure I described. If you don’t do that, you could still have high-deductible health insurance with considerable cost sharing, coupled with health savings accounts that are tax-preferred. How would you make it more humane? First of all, you could limit the out-of-pocket exposure a family has to a fraction of its income. You could say, no family should be asked to spend, in any given year, more than 15% of its income on health care, and for poor people, you might even set that bar lower. On the health savings account issue, the law could stipulate that for every American, rich or poor, who puts a buck in there, they get a 30% refundable tax credit. That would make it at least horizontally fair. And you could even give a fifty cent tax-credit subsidy to poor people and not allow families with incomes in excess of, say, \$150,000 to make any deposits out of pre-tax income. To make it fair *vis à vis* employer-paid insurance, you could put that limit in there as well.

WHLE: Critics have also argued that CDHPs will place an undue financial burden on patients who are chronically ill. Can you comment on this concern?

UR: There’s no question it will do that. The bulk of health spending – 80% of health spending – is done by the 20% of Americans who are the sickest people. Most families spend considerably less than \$4,000 a year on health care. So if you have a \$5,000 deductible, a chronically healthy family would basically have at most \$1,000 out-of-pocket, and it could sock away \$4,000 every year if they had it in a tax sheltered health savings account. A chronically ill family with one or two members on high-cost medicines that needs frequent hospitalization, they would blow their deductible year after year out of pocket, so their out-of-pocket spending would actually be \$5,000 year after year. Relative to what we have now, you would shift more of the financial burden of health care onto the shoulders of chronically ill people. Does this really reflect the social ethic of the American people?

WHLE: Do you think this is an intractable issue, or could it be resolved by changes to the

current plan structure?

UR: Again, you could do something by at least limiting that out-of-pocket exposure to a percent of income. But taking care of the chronically ill, unless you could somehow figure out or rate how chronically sick people are and on the basis of that, give them risk-adjusted public subsidies, then if you could do that, you could certainly mitigate shifting the burden to the sick. Is that impossible to do? Not necessarily. The Veterans Administration rates the disability of veterans and bases disability payments on the degree of disability. You might be able to do something like that for the chronically ill, but it would require a fair amount of extra paperwork and bureaucracy. But it could be done.

WHLE: Now I'd like to move on to the current political environment. Many observers believe that the newly-elected Democratic Congress will have health care issues prominently featured on its agenda. What do you

think the new vision will be for health care at the national level? Do you foresee any exhaustive health care reforms coming up?

UR: First of all, to the latter question, exhaustive health care reform – I say no. You cannot do health reform unless you have a President who cares about it. So what you need is to have the interests of the Congress and the President in line, and the President and the Congress have to basically work together. President Bush has shown amply that he has little interest in health reform, other than to tinker with a few dollars (less than \$10 billion a year) of subsidies for the poor, coupled with more sizeable tax-forgiveness for higher-income people, through the HSA tax preference. With all respect due the President of the United States, I would not call that much of a health policy. At the moment, for the next

two years, not much will be done at the federal level. What will probably get done is that the HSA movement will be stopped dead in its tracks. What also will get done is that the shift of Medicare patients into Medicare Advantage will be considerably slowed down, if not stopped dead in its tracks. As is well known, the Medicare Advantage plans were paid more per beneficiary by Medicare than that beneficiary would have cost in traditional

Medicare. I would expect the Democrats to kill that subsidy and use the savings to pay doctors and hospitals a bit better.

You might see movements to cover the donut hole for prescription-drug coverage left uncovered in the Medicare Modernization Act of 2003. Of course, that's politically rewarding for both parties, and I could see a fair number of Republicans in say Phoenix, Arizona or in Florida, where there are many Medicare beneficiaries, going along with a gig like that. You could see a Republican Congressman vote for filling the donut

hole given how many elderly they have there. And the Democrats would be for it for ideological reasons. So you might get that done. Then again, President Bush might just veto everything if he's got nothing to lose and he's angry. He's just not a leader in health care. He might veto things because he may of late discover the deficit that, let's be honest about it, his fiscal policies during 2001-2006 had caused, and say that we can't be irresponsible here and spend more money on Medicare.

WHLE: Given that you don't think many things will happen at the federal level in the next two years, do you think that state-based innovation will be an important driver of health care reform?

UR: Very important. You've already got the Massachusetts initiative, and California and

"How would you make [CDHPs] more humane? First of all, you could limit the out-of-pocket exposure a family has to a fraction of its income. You could say, no family should be asked to spend, in any given year, more than 15% of its income on health care, and for poor people, you might even set that bar lower and subsidize them outright to achieve it."

Pennsylvania following suit. Yet other states will have to somehow find ways to make the given health care dollar be more efficient, which probably means Medicaid reform, but not in the way that the recent Medicaid commission recommended. The problem with those state initiatives, imaginative as they are, is that all of them rest on very shaky fiscal platforms and, therefore, might have a short use life, just as earlier initiatives like that in Oregon and Washington had. Here the Feds could help by granting the states more financial assistance.

WHLE: What is your evaluation of the Massachusetts health plan?

UR: It's an ugly duckling, to be sure, but it's the American way in health insurance and, therefore, I endorse it. Americans seem to like it this way – very complex, very fiscally fragile, mind-boggling in its bureaucratic implications and with very high admin-

istrative costs which are, however, someone's income. We do have the most bureaucratic health system in the world by far, and the Massachusetts plan continues that hallowed tradition. It sort of fits that mold. Other states can and will copy it. We should remember, though, that Massachusetts

is a relatively rich state with relatively few uninsured. Furthermore it is a small state where people know each other, and can cooperate with one another. You cannot imagine Louisiana being able to do this without an awful lot of federal intervention of two sorts. One, federal money, and, two, with it a federal two-by-four hanging over the state's head: "If you don't do this, you won't get this money." In theory, this sort of thing could work, so that the feds would mainly be funding it, and the states would administer it according to their tastes, a bit like Medicaid on waivers.

"[The Massachusetts health plan is] an ugly duckling, to be sure, but it's the American way in health insurance and, therefore, I endorse it. Americans seem to like it this way – very complex, very fiscally fragile, mind-boggling in its bureaucratic implications and with very high administrative costs which are, however, someone's income. We do have the most bureaucratic health system in the world by far, and the Massachusetts plan continues that hallowed tradition."

PLAN B: Unraveling the Process and Politics of Drug Regulation



PETER BARTON HUTT is a senior counsel in the Washington, D.C. law firm of Covington & Burling LLP specializing in food and drug law. He graduated from Yale College and Harvard Law School and obtained a Masters of Law degree in Food and Drug Law from NYU Law School. Mr. Hutt served as Chief Counsel for the Food and Drug Administration during 1971-1975. He is the co-author of the case-book used to teach food and drug law throughout the country, and has published more than 175 book chapters and articles on food and drug law and health policy. He teaches a full course on this subject during Winter Term at Harvard Law School and has taught the same course during Spring Term at Stanford Law School.

Mr. Hutt has been a member of the Institute of Medicine since it was founded in 1971. He serves on academic, philanthropic, and venture capital advisory boards, and the boards of startup biotechnology companies. He has received numerous honors, including being named by the *National Law Journal* as one of the 40 best health care lawyers in the United States. In April 2005, Mr. Hutt was presented the FDA Distinguished Alumni Award by FDA Commissioner Crawford. Here, Mr. Hutt examines the controversy surrounding the over-the-counter approval of Barr Labs' drug, Plan B, and its implications for the regulatory environment moving forward.

WHLE: For the benefit of those who are unfamiliar with the legal aspects of drug approval, we would like to start by understanding some of the relevant frameworks. The Durham-Humphrey Amendment to the Federal Food, Drug, and Cosmetic Act was enacted in 1951 to set up standards for classifying over-the-counter versus prescription drugs. Can you give us some background on this important legislation?

PBH: Prior to the Federal Food, Drug, and Cosmetic Act of 1938, no distinction was made in federal law between an over-the-counter (non-prescription) drug on the one hand, and a prescription drug on the other hand. The decision whether to sell a drug as prescription or non-prescription was entirely a marketing choice made by the manufacturer. As part of the 1938

Act, however, Congress added one provision that changed this approach. Although there was no legislative history indicating that it was intended to change anything, Congress included in the 1938 Act a provision stating that every drug must have a label stating, among other things, "adequate directions for use." Six months after the 1938 Act was enacted, FDA promulgated a regulation interpreting that requirement in the following way: "adequate directions for use" mean adequate directions for lay people to use the drug, and for drugs for diseases which lay people cannot self-diagnose and self-treat, FDA would exempt those drugs from the requirement for adequate directions for use upon the condition that they be sold only on prescription. Thus, FDA created out of whole cloth, and clearly contrary to the intent of Congress, a mandatory prescription status.

Between 1938 and 1951, FDA attempted to use that regulation to control whether a drug was marketed as prescription (Rx) or over-the-counter (OTC), but the marketplace was out of control, and you could find the same drug sold both prescription and over-the-counter for the same indication and at the same dosage. In the early 1950s, one person in particular, a pharmacist named Hubert Humphrey, concluded that order ought to be brought out of chaos in the pharmaceutical marketplace.

The Durham-Humphrey Amendment of 1951 amended the 1938 Act to incorporate the policy established by FDA and thus to enact the current statutory distinction between an over-the-counter and a prescription drug.

There are three statutory criteria for the distinction between an Rx and an OTC drug. First, is it a drug of abuse? Second, is there a safety issue? And third, are there so-called “collateral measures” (that is the statutory term) that would lead you to conclude that a physician should be involved in prescribing the drug. It’s the latter category which is extremely broad. There is no definition of “collateral measures,” and if you read the legislative history, you will be equally disappointed – you will not find any useful, substantive indication of what was intended. That is the origin of the distinction between an Rx and an OTC drug.

WHLE: What is the current regulatory framework for companies who are switching products that are initially on-prescription to non-prescription status, and who are considering placing these products behind-the-counter?

PBH: As a matter of law, FDA and the statute have nothing to do with that. Whether a non-prescription drug is placed in front of or behind the counter is a marketing decision. It is entirely

up to the manufacturer, to figure out which way to market a non-prescription drug.

WHLE: If you have a company like Barr Labs trying to switch a prescription drug to non-prescription status, to what extent can the FDA consider this behind-the-counter issue versus it just being generally available anywhere in the pharmacy?

PBH: There is an informal, non-statutory basis for taking this into consideration. I am

sure you realize government agencies can take action that is not explicitly permitted by statute. Here is the kind of scenario that undoubtedly happened with Plan B. I am sure that Barr came to FDA and said, “We want it OTC.” And I am sure the FDA then made it clear, directly or indirectly, that “If you want it OTC, we would be prepared to approve it if you volunteer to put it behind the counter, but if you do not, it may take us a long time to consider this.”

WHLE: Historically, it has been unusual for the FDA to make a decision

that goes against an advisory committee recommendation. What factors do you think influenced the decision in the case of Plan B?

PBH: First, it has not been unusual.

WHLE: This is good for us to know, because as it has been reported, there has been an impression that it has been unusual.

PBH: Somewhere between 75 and 95% of the time, FDA follows an advisory committee. It depends on whether you include each advisory committee intermediate recommendation or only the final recommendation. But on many important issues, they will not follow the advisory committee, and thus, it is not at all unusual. None of us who follow this every day regard that as an unusual event. The FDA does not lightly ignore an advisory committee. That is quite clear. But you must remember that an advisory committee

“The decision to switch a drug from Rx to OTC status has never been a scientific decision. It is a mixed decision of policy, medicine, regulation, law, and the personal bias that everybody has...This is the kind of issue on which personal judgments about morality, medical care, and all kinds of other questions come into play.”

The Plan B Approval Process: Major Milestones From 1999-2006

The FDA originally approved Plan B as a prescription drug in 1999.

An advisory panel to the FDA recommended approval of Plan B as an over-the-counter drug in late 2003. However, the decision on Plan B was delayed by the FDA.

Senators Patty Murray (D-Wash.) and Hillary Rodham Clinton (D-NY) blocked Lester Crawford's nomination as FDA commissioner, but allowed Crawford to be confirmed after Mike Leavitt, the secretary of health and human services, promised that the FDA would make a decision on Plan B.

However, in August 2005, then-commissioner Lester Crawford postponed the decision on Plan B indefinitely.

Crawford resigned his post one month after putting the application on hold.

After President Bush nominated Andrew von Eschenbach, the acting commissioner of the FDA, to be the next FDA commissioner, Senators Murray and Clinton announced their intention to block his nomination as FDA commissioner until a final decision was made.

In August 2006, the FDA approved Plan B for non-prescription behind-the-counter sale at pharmacies staffed by a licensed pharmacist for women ages 18 or older.

Source: "FDA Weighs Wider Access to Morning After Pill." Associated Press. July 31, 2006. www.msnbc.com.

does not have all of the detailed facts, has not been studying the matter for a year (it has been studying it for probably about three hours), and is not comprised of regulatory experts. Thus, there are many occasions when FDA concludes that as much as they like to have an advisory review, they disagree with the advisory committee. It is to be expected on occasion.

You might then ask, "Okay, what happened with Plan B?" The first thing you must do is go back to the criteria for an Rx to OTC switch. The decision to switch a drug from Rx to OTC status has never been a scientific decision. It is a mixed decision of policy, medicine, regulation, law, and the personal bias that everybody has. I happen to have been biased in favor of making the switch for Plan B, but I ascribe no bad motives whatsoever to people who concluded differently. This is the kind of issue on which personal judgments about morality, medical care, and all kinds of other questions come into play. These are what the statute calls "collateral measures." And there-

fore, it is to be expected that reasonable people will differ, because it is not a black box, it is not a mathematical formula, it is not pure science. When you say, what should be the factors, there is no limit to the number of factors that can be considered in an Rx to OTC switch.

WHLE: What factors do you think influenced the decision in this case?

PBH: I think genuine concern for the doctor/patient relationship, genuine concern for the parental responsibilities for young people, genuine concern for the safety and protection of vulnerable teenagers, and a whole collection of related considerations. And those are the kind of collateral measures that lead to the conclusion, in the opinion of some, that this kind of drug should be available only on the prescription of a physician. That is the reason for the age differentiation. I am not saying that they are right. I am saying that these were factors that people, in good faith, genuinely thought were the right factors to consider. They are not bad or uninformed people. In fact,

they are extraordinarily bright, well-intentioned, and nice people. And as much as I disagreed with them, I admire them, and they remain friends of mine.

WHLE: Related to these factors, opponents of Plan B's over-the-counter approval contended that the product would encourage people to engage in riskier behavior and to use the product as an alternative to other methods of birth control. To what extent is the FDA allowed to consider potential consequences such as these, which may have negative effects but which do not constitute abuse of the product in the traditional sense?

PBH: In my opinion, they can. And in my opinion, that is the reason Congress came up with this highly ambiguous "collateral measures" language, which is not defined and has no intrinsic meaning whatsoever. You can search the entire legislative history, and you cannot find a single sentence that bears upon what this was intended to mean.

WHLE: So within that, they do have the flexibility to consider all of these other things?

PBH: Yes. There was a lot of discussion about legislative language at one point about how FDA could only consider science, but then Congress later changed the law to open it up.

WHLE: What about age requirements? Patients must be at least eighteen years old to purchase Plan B over-the-counter at a pharmacy. How common is it for a product to carry an age requirement like this? Is it difficult to enforce such a requirement, and what is the FDA's ability under the law to consider enforceability in its approval decisions?

PBH: It is uncommon, indeed, it is rare. I would distinguish this from when I said earlier that it was not unusual for FDA not to follow the advice of an advisory committee. It is very unusual, in my judgment, that you would have an age restriction. In fact, Congress usually is the group that imposes age restrictions, for example, on items such as tobacco and liquor. FDA frequently places age-related information on drug labels – for example, related to pediatric or geriatric use – but this does not function as a restriction that is intended to be enforced.

WHLE: Given that it is rare, what is



the FDA's ability under the law to consider enforceability of the age limit and to consider such an age limit in the approval decision of non-prescription products?

PBH: FDA has little or no ability to enforce it. But the fact is that FDA requires restrictions on labels all the time that it cannot enforce. If you buy an over-the-counter drug and it says, "Do not use more than two pills a day," some people might take three. There are labels on prescription drugs that not only say "warning," they say "contraindicated." That means under no circumstance prescribe this drug for X, and yet doctors will prescribe it for X because they exercise their judgment that it is more likely to be a benefit than a risk for a particular patient.

FDA does not enforce these restrictions, and yet it frequently requires them on the label. The agency as a practical matter is not going to try to enforce them. But there are pharmacists, who dispense drugs, and pharmacists are licensed by state law in the same way that lawyers are licensed by state law. If you commit violations of law, or if you are unethical, you can lose your license. Moreover, there is something called tort law. If the pharmacist fails to card a young woman and wrongly gives her a drug with an age restriction and something adverse happens to

her, that pharmacist has no defense whatever to a product liability or a malpractice lawsuit. There is even some doubt that the pharmacist would be covered by insurance in the event of a direct violation of federal law. The fact is that pharmacists are trained to be ethical, they are trained to protect patients, they are trained to follow the labeling, and that is why, although FDA is not going to enforce an age restriction, that does not mean there is no enforcement.

WHLE: Plan B is a two-dose drug that prevents ovulation, fertilization of an egg or, in some rare cases, the implantation of an embryo, while the regular birth control pill is taken on a daily basis to prevent ovulation. However, Plan B is essentially a higher dose of the same ingredients in some oral contraceptive pills. Senator Tom Coburn has questioned the logic of the approval, saying in a statement, “Never before has the FDA approved a medicine for over-the-counter sales when a lower dose of the same drug requires a prescription.” What are the legal implications, if any, of approving something in a higher dose than it is available by prescription?

PBH: That is a factually true statement, but the active ingredient used in these two drugs is used under very different conditions. For one, the drug is going to be used once. For the other, it will be used for an entire lifetime. Therefore, the two uses are not comparable.

WHLE: Finally, we would like to ask you to take off your law professor hat and put on the hat of industry drug developers and research scientists. What does the Plan B case study mean in terms of the future of FDA regulation, specifically the challenges of bringing controversial drugs to market?

PBH: What it means to me is that any time that you have a new category of a non-prescription drug, you’re going to have a difficult time.

Let me give you two examples. I spent five years helping Burroughs-Wellcome try to switch the drug, Zovirax, that is used for herpes, from prescription to over-the-counter status. We knew that this would be an extraordinarily difficult sell, for all of the collateral measures reasons that we have been discussing. This was a new category that would require men and women to differentiate herpes from other types of sexually transmitted disease. We thought that the public health would be tremendously advanced by having this drug switched to OTC status, because there would be very effective treatment available for people who did not wish to discuss their condition with a

physician. But that was not enough to win the day. We lost that fight.

Fast-forward to Lovastatin/Mevacor sold by Merck. I have spent the last six years assisting Merck in trying to switch the first statin from prescription to non-prescription status. This one, to me, is infinitely easier. Yet the whole concept of people self-treating for heart disease simply sets doctors on edge. “What are you going to do now – have people self-diagnosing and treating

cancer? This is getting out of control!” That was their argument.

My argument is just the opposite. Prescription statins are only treating a small percentage of the number of people whose lives could be saved if they were on a statin. It is an American and a worldwide tragedy that we still have the level of heart disease that we do. We ought to be putting statins in the water supply – that is how safe and effective they are. But we do not have FDA over the line yet. I know that Mevacor will be switched, but I do not know whether it will be in a year or in ten years. And people will look back and say the failure of FDA to do this earlier has needlessly cost millions of lives. There is no doubt in my mind about this.

"We ought to be putting statins in the water supply – that is how safe and effective they are. But we do not have FDA over the line yet... [P]eople will look back and say the failure of FDA to do this earlier has needlessly cost millions of lives. There is no doubt in my mind about this. "

Rise of the Market

HOW THE INFORMED SHOPPER IS CHANGING HEALTH CARE



What does consumer-driven health care look like? To our minds, it resembles the modern eye-care industry, in which patients demand convenient service, high quality and low costs. Just as eyeglass frames have become lighter, more flexible and more stylish, in today's market, every health care interaction will lead providers to deliver service based on what consumers want. We looked to examples at home and abroad to understand the nuances of this important trend. One of the first examples of a market response includes retail-based clinics staffed by nurse practitioners. **REVOLUTION HEALTH CMO JEFF GRUEN** shares his hopes for these clinics that are popping up in retail pharmacies, grocery stores and big box retail outlets. **PROFESSOR REGINA HERZLINGER** has a track record of success when it comes to predicting the rise of the market in health care. She shares her vision for the future of this important movement and emphasizes the centrality of information as power. As health care outcomes data is finally being collected and shared, our article on **CONSUMER INFORMATION** describes how consumers are increasingly gaining access to this data, and how payers have facilitated this process. American providers who balk at this push towards transparency, even if they band together through professional and industry organizations, will find that the world truly is flat. As we describe in an adjacent article on **MEDICAL TOURISM**, foreign providers are proving – through their commitment to transparency in both quality and price – that they offer worthy alternatives to America's health care system.

Medical Tourism: Things being Equal, I'd Rather Be In Bangkok

W H L E EDITORIAL



An Increasingly Viable Alternative

Not long ago, a futurist could shock an audience of health care leaders by telling them that someday Americans would fly 10,000 miles around the world to have major surgery in India. “Ridiculous!” the crowd would cry, “patients demand U.S. quality, all health care is local, and they don’t care about costs because of the third-party payment system.” Today, however, there are providers around the globe that rival any hospital in the States on quality, charge a fraction of the price (even including airfare), and cater to a clientele who are bearing more of the direct (and rising) costs of their own health care. Last year, half a million Americans received health care services in another country. The driver behind this trend is cost.

Medical tourism ceased to be a futurist’s fantasy and became practical reality when the Joint Commission (JC) launched its international branch, Joint Commission International (JCI) in 1999. Now certifying over 70 hospitals around the world, JCI has bestowed legitimacy on medical tourism. Since then, new businesses, existing payers, even state governments began exploring

how they can reap the benefits of geographic price differentials. According to the National Coalition on Health Care, more than 500,000 Americans chose offshore medical treatment in 2005.¹ McKinsey & Company estimates that in India alone, medical tourism revenue could hit \$2.2 billion by 2012.²

In response, the Indian government has gone so far as to publicly encourage medical tourism by offering one-year extendable medical visas, organizing exhibitions to showcase Indian hospitals, and creating a list of recommended hospitals to attract foreign patients.³ The Apollo system in India, for example, boasts the same surgical success rate as the Cleveland Clinic.⁴ Escorts Heart Institute and Research Center in Delhi and Faridabad, India, performs nearly 15,000 heart operations every year, and the death rate among patients during surgery is only 0.8% - less than half that of most major hospitals in the United States⁵.

But India is playing catch-up to other countries that already have a reputation for world-class care. Bumrungrad International Hospital in Bangkok is probably the best-known, receiving

popular media-coverage in newspapers around the world and even on NBC’s Today Show. Newsweek rated it among the top ten international hospitals, due in part to 200 U.S.-trained physicians and amenities like a spa, a sushi restaurant, and, as in so many American hospitals, a McDonald’s a Starbucks.⁶ They treat 400,000 foreign patients a year, 50,000 of whom are American and the numbers are growing quickly.⁷ The patients who experience Bumrungrad realize that low cost and good outcomes are not its only points of differentiation. It also provides world-class customer service and patient satisfaction. Patients pay tribute to these competencies in testimonials and repeat business, and anyone who visits its website can pick up on cues of world-class consumer-focus. The only reason that this publication knew Bumrungrad wasn’t an American hospital was that its website was actually consumer-friendly. The website is easy to navigate, provides quick access to health care professionals, and, unlike any hospital found in the United States, offers pricing transparency. In a section titled “Packages and Pricing” on the front page of www.bumrungrad.com, this publication learned that a complete diagnostic cardiac angiogram could be performed for 45,000 bhat (roughly US \$1,231). As an international patient, one could have access to a full suite of concierge services, including a private secretary for dictation, video and music entertainment, and laptop rental with Internet access. Of course, international patients also have access to interpreters who speak an array of languages from Arabic to German to Japanese (English is taken for granted). Try finding a four-star hotel in the US that offers the same level of customer service as Bumrungrad International Hospital.

Professor Regina Herzlinger of Harvard Business School cheers on these alternatives to the US health care system, “If we can’t get competition in United States because hospitals are so powerful that they will block competition in myriad ways, its wonderful that we’re going to get competition from very competent providers in India, Thailand, and Mexico and Central and South America. They will really shake up the market” (see page 24 for the complete Q/A interview with Professor Herzlinger).

Cost Comparison: North America, India and France

PROCEDURE	LOCATIONS		
	N. America	India	France
Medical			
Heart bypass	\$100,000	\$7,000	\$33,100
Coronary angioplasty	\$35,000	\$3,700	\$18,400
Hip replacement	\$40,000	\$5,800	\$15,000
Knee replacement (single)	\$35,000	\$6,700	\$17,000
Laparoscopic gastric bypass	\$30,000	\$16,500	N/A
Rotator cuff repair	\$40,000	\$3,700	N/A
ACL repair	\$17,000	\$3,700	N/A
Cosmetic			
Breast augmentation	\$5,000	\$2,500	\$9,600
Breast lift	\$9,000	\$3,000	\$7,000
Breast reduction	\$4,000	\$2,100	\$10,000
Face lift	\$8,500	\$2,500	\$12,300
Liposuction	\$7,000	\$1,750	\$7,900
Nose job (rhinoplasty)	\$4,200	\$2,250	\$7,000
Tummy tuck (abdominoplasty)	\$6,400	\$2,500	\$7,900

Note: Prices may vary. Source: MedSolution.com

Source: www.medsolution.com. Please note that costs reported exclude airfare and hotel costs. North America includes the US and Canada.

JCI standards for hospitals include assessing quality of patient care, efficiency and best practices of management, patient safety standards, and improvement across key functions.⁸ Although specific information on the JC and JCI evaluation methodologies are not publicly available, the criteria for JCI accreditation are considered as rigorous as they are for US hospitals seeking JC accreditation.⁹

Only 71 international hospitals have received JCI accreditation.¹⁰ But if a hospital can achieve the JCI designation, the significant investment of time and capital is likely a smart one. At the time of this publication, traditional American health plans hesitated to reimburse JCI-accredited hospitals, and Medicare in particular would only reimburse American providers, but a crop of start-ups has begun to test the offshore waters. With names like MediEscapes India and MedRetreat (“Where smart medicine and exotic travel come together”), these small entrepreneurial ventures are conducting market experiments with business models that, if successful, could be rolled out by the UnitedHealths and Humanas of the world.¹¹ The best known of this new breed is Planet Hospital, which claims to be the first US-based medical tourism outfit recognized by the Better Business Bureau.¹² One of the differentiating features of Planet Hospital is that it offers to coordinate travel for both patients and his/her

physician, thus minimizing any interruption in the continuum of care. The only thing that changes is the hospital. By carving out the fattest part of the value chain, Planet Hospital can provide win-win opportunities for the patient, the physician and the overseas hospital

Currently, only small employers are participating in contracts for overseas care. As described in a *USA Today* article, “Florida United Group Programs recently began promoting surgeries at one Thailand hospital as an option for its employer clients, saying it can save as much as \$60,000 to \$70,000 for a routine bypass procedure.”¹³ Some of these efforts are running into opposition from union labor groups who fear that what today is an option might someday become mandatory. One North Carolina employer decided not to send an employee to India for gallstone and rotator cuff surgery after the United Steelworkers Union filed a lawsuit to prevent the action.¹⁴

A Model for Payers

This union may have prevented that particular surgery in North Carolina, but it cannot stop them all, specially now that state legislatures are intrigued by the concept. In 1998 and 1999, the State of California passed laws legalizing and regulating HMOs that offer patients the option to receive the majority of their non-emergent care

in Mexican facilities – in exchange for premiums that may cost half that of traditional plans.¹⁵ In an article for the Washington Post, Sonya Geis reports that as of November of last year, about 20,000 Californians have signed up for these plans and the number is growing at 15% per year. Texas introduced similar legislation that was shot down by physician lobbies who claimed they could not hope to compete with Mexican prices. For the U.S. firms who sponsor these HMOs, including Blue Shield of California, SIMNSA and HealthNet, “[l]ower labor costs, overhead, and malpractice insurance premiums” in Mexico create “the kind of affordable monthly premiums most American businesses have not seen in a decade.¹⁶” Perhaps what is most notable is not that the people featured in Geis’s article referenced the high quality of the Mexican facilities, but that they actually prefer the care:

“I went to the doctor over here and he never cured the problem, he never gave me a good medicine, never sent me to a specialist. He never cared about my health,” Gonzales said. “When I went over [to Mexico], the first doctor I saw, he sent me to a specialist. He wasn’t just going to say, ‘Take this and go home.’”

One of the most surprising developments in medical tourism is what happened in the West Virginia State Legislature earlier this year. In

United States Academic Medical Centers (AMC) Explore Partnerships Abroad

AMC	US Location	Partner Country	Partnership Terms (C,E,R)*
Duke University	Raleigh, NC	Singapore	C, E, R
Harvard University	Boston, MA	United Arab Emirates	R
Johns Hopkins University	Baltimore, MD	Singapore	C, E, R
University of Pittsburgh	Pittsburgh, PA	Ireland, Italy, Qatar	P, E
Cornell University (School of Medicine)	New York, NY	Qatar	E
Cleveland Clinic	Cleveland, OH	Saudi Arabia, United Arab Emirate	C
New York Presbyterian	New York, NY	United Kingdom	C

***Partnership Terms Key:**
C = Patient Care
E = Medical Education
R = Research

Source: University and hospital websites and press releases. Specific partnership terms may have been further developed since the time of this publication.

February, Rep. Ray Canterbury in West Virginia (R-Greenbrier) introduced House Bill 4359 “establishing a system to reduce the cost of medical care paid by the Public Employees Insurance Agency by providing incentives to covered employees to obtain treatment in low cost foreign health care facilities accredited by the Joint Commission International.”¹⁷

In other words, state employees who agree to undergo major surgical care in India would be eligible for free airfare, lodging, surgery, sick leave, and a companion of their choosing. They would be exempt from co-pays, deductibles, and, perhaps most compelling of all, they could receive up to 20% of the savings that the state would realize by not using local hospitals.¹⁸ It is unclear whether this bill will become law in West Virginia, but we do know that the legislature is taking it seriously. It even invited Planet Hospital to the Charleston statehouse to present a proposal for the administration of such a policy.

All of these efforts combine to suggest a real opportunity for payers. One conservative estimate in *Health Affairs* suggests \$2 billion in savings could be realized if a fraction of Americans went overseas for one of 16 different procedures that the authors believe are easily tradable. That includes everyone from self-pays to employers to Medicare. To realize these savings, overseas providers will have to overcome several more obstacles. Until foreign providers can convince Americans of their indigenous quality, patients can be put at ease by knowing that their foreign physicians are US-trained. In addition, teleconferences between the patient, the patient’s US physician, and a foreign physician can assure the patient that the US and foreign physicians agree on the procedure that needs to be done for the patient.

Ensuring the Viability of a Growing Industry

The physician is the critical element in any significant care model. What do they think about medical tourism? Will they be comfortable working with physicians from across the world who are not subject to the stringent rules and legal liabilities of American physicians? Would physicians in the US be willing to see patients for follow-up visits if they did not perform the surgery themselves? Would patients feel comfort-

able having one physician perform the surgery and another doing the follow-up visits? Health plans fostering this international effort might respond to this challenge by bringing foreign physicians in-network so there is a built-in connection between the physicians.

The lack of legal recourse against providers in other countries remains a major obstacle. Ultimately, patients will have to do their own careful research about specific international providers, just like they do with US providers, to assure themselves that they are receiving the safest care they can afford. If a person’s reluctance to travel outside of US jurisdiction outweighs the utility of the cost savings, he/she will not go. It remains to be seen what the elasticities actually are in this space.

Recognizing that the length and discomfort of commercial flights should not be discounted as a depressor of utilization, health plans and foreign providers could help ameliorate the strains of travel. Paying for first-class seats is one popular approach. But flights also present a potential medical concern, leaving people without medical care while the plane is over the ocean.¹⁹ With their large base of subscribers, though, health plans in particular could aggregate their traveling patients and provide them with specialized, chartered planes, staffed by nurses to provide in-flight care.

With such a strong economic case, it is only a matter of time before consumers and the groups who fund their health care learn to reap the rewards of globalization. It is this publication’s view that they will do so as soon as first-movers like Planet Hospital demonstrate the viability of this model. Our early investigation into the liability issues suggests that payers have little to fear from legal action, though the concept is so new that the relevant case law is ambiguous at best, and businesses will need legal counsel at every step. Ten years from now, unless governments and regulatory bodies capitulate to protectionist temptations, the large health plans will have copied the successful experiments that start-ups like Planet Hospital discover. One can hope that greater global competition will do for health care what it’s done for electronics and automobiles – spur continuous innovation, heighten quality, and lower prices.

Consumerism and Health Care: Expecting the Unexpected



Perhaps the most outspoken advocate of consumer-driven health care is the woman widely credited with coining the term, Harvard Business School's Professor Regina Herzlinger, Nancy R. McPherson Professor of Business Administration. She was the first woman to be tenured and chaired at Harvard Business School and the first to serve on a number of corporate boards. She is widely recognized for her innovative research in health care, including her early predictions of the unraveling of managed care and the rise of consumer-driven health care and health care focused factories, two terms that she coined. Money magazine has dubbed her the "Godmother" of consumer-driven health care. Regina Herzlinger received her Bachelor's Degree from MIT and her Doctorate from the Harvard Business School.

Her most recent book, *Consumer-Driven Health Care: Implications for Providers, Payers, and Policymakers* (San Francisco: Jossey-Bass, 2004), was profiled in "Are you ready to own your health care?" *Money Magazine*, November 2004, and received the 2004 American Journal of Nursing Book of the Year award for History and Public Policy.

Her upcoming book, *Who Killed Healthcare?* will go on sale this Spring. Here, she shares with us her assessment of the consumer movement, including key successes, important discoveries and untapped opportunities.

WHLE: Market-Driven Health Care came out a decade ago as a clarion call to the industry to behave like a real business that cares about its customers. Nearly ten years on, who is heeding this call? Who isn't? Any surprises about what has or hasn't occurred?

RH: I think the insurance industry has been the most responsive through the introduction of these high-deductible health plans. It's astonishing that a trillion dollar industry would offer one product, but now insurance companies are serious about putting assets in place that will enable them to sell at least another type of product. United bought Exante Financial Services, Definity and Wellpoint bought Lumenos, and Aetna has been serious about making at least some price information apparent. You can't have a well-functioning market without transparency. So all of that has been great.

There's also been an industry started that I call the "neutral intermediary." These are neutral competent third parties who help consumers shop. In the automobile industry, analogues would be Consumer Reports and JD Power. WebMD has

been serious about [playing this type of role] and they acquired a company started by one of my former students called Healthshare Technology. He is a CPA/MBA, and the company has risk-adjusted morbidity and mortality data by procedure, by hospital [to answer questions like], "What are the chances of dying in each of the seven hospitals in Northern Virginia. What are the chances of needing readmission? What's the morbidity status of people 30 days after hospitalization?" It's not the insurer's mastication of this kind of data, it's the kind of information that people want to look at.

It's an oxymoron that an industry with the GDP of China has as primitive technology as it does. But that is changing with WebMD recently buying Subimo [a provider of health care decision support applications to large employers, health plans and financial institutions] for \$60 million, which is great for the entrepreneurs involved to see a great exit strategy if they want it. There are also under-the-radar companies like Wageworks and SHPS that provides the engines to run HSAs and HRAs and FSAs. I've been cheered by the

willingness of VCs to back these kinds of companies. Years ago, Definity was started around 2000, there just weren't a lot of people who understood what the heck this was. Now the venture capitalists and the private equity players are getting much more sophisticated about this space, which again is very important because if they don't know what they're doing and they invest in funds and they lose their shirts, the next round of investing is going to be hurt by that.

WHLE: What are the primary obstacles to consumer-driven health care?

RH: The biggest impediment of course is the hospitals. The US hospital sector is vastly more inefficient than any other in developed countries.

They have managed to block competition in two ways. One way is through mergers which have not resulted in economies of scale. Typically consolidation results in economies of scale, but these mergers have clearly been oligopolistic or monopolistic to protect their pricing power. The second thing they have done is use their considerable political power to block even minor innovations like the specialty hospitals. I view them as major impediments and really outrageous. The way they are outrageous is that they use their non-profit status to assume a mantle of undeserved sanctity. There are many wonderful people who work in hospitals so this is not about the people, but institutionally their behavior is very far from saintly, not only in anti-competitive tactics but also in their dealings with the uninsured and their relentless opposition to any kind of transparency. You know, very formidable anti-market tactics.

WHLE: There has been a backlash to hospitals from activists such as KB Forbes and from congressional actions designed to test the

not-for-profit status of hospitals which earn millions in total margins . . .

RH: There has been backlash but there has to be much more. One movement on the horizon I'm very happy about is that Congress lifted the moratorium on specialty hospitals. Suppose IBM said, "Don't let Michael Dell be in business, he's going to hurt me." People would find that ludicrous. If Michael Dell is better and cheaper, you know, go ahead and do it. But somehow that Congress would buy the argument that because specialty hospitals are at least as good and cheaper than the general hospitals we should bar them from existence is an outrageous argument.

WHLE: What are the appropriate roles for government to play

in this movement?

RH: One is the tax equity so that whether I buy health insurance or Harvard University buys it on my behalf, I'm using the same tax-exempt dollars. And the second is that the government will insist on transparency in outcomes.

In my book I focus on kidney disease, which is paid for by Medicare. People who have dialysis become anemic, and the drug EPO, an Amgen drug, is helpful in managing anemia. A key marker of anemia is the hematocrit [the proportion, by volume, of the blood that consists of red blood cells], so Senator Arlen Specter of Pennsylvania puts out a huge campaign to raise the target hematocrit levels from 32-36% to 36-39%. To raise the hematocrit three percentage points requires doubling the dose of EPO. And when he did it, there was no clear evidence that it was helpful, and some physicians thought it would be harmful. The *New England Journal of Medicine* had an article about how raising the level of EPO causes heart attacks and other undesirable side effects. So when you have this kind

of micromanagement by the federal government you have the kind of irony of Sen. Specter, who is a very able man, so I'm not out for Specter – but what qualifies him to tell a physician who has a patient with a kidney disease – a very dangerous disease – what the hematocrit levels ought to be? That's what we've come to and we just focus on process rather than focus on outcomes.

And what I like to say is that I don't care how my car was made, I have no interest in it.

What I want to know is, is the car safe, is it reliable, fuel-efficient, environmentally friendly, how much does it cost? I'm very interested in outcome measures not process measures but process is how bureaucrats can reign in the medical system and control it. And process is how ivory tower academics who believe that they are better than the clinical doctors gain control over them.

It's very frustrating.

There's already some early literature on it. The bottom line is that if Congress or an insurer takes your money from your salary and then does it out ostensibly on your behalf, they're going to call the shots. Their thought process is that the more control they have the better it will be. In fact all evidence is to the contrary. The only way to undermine the coalition that really loves the power it has right now is to let consumers have control. To take all that money away from the groups who ostensibly act on our behalves but who have abused - not maliciously - but have done what human beings will do, and that is to say, "I'm smarter than you. You gave me the money. I'm going to cut the actual providers and consumers out of the action."

GOVERNMENT ACTIONS

I expect a number of people were surprised with what the US Congress has done with HSAs [but there is much more to be done]. Switzerland, which has consumer-driven system – consumers

do the buying rather than a third-party buying on their behalf – has a much broader variety of health insurance policies. [In Switzerland], only 40% of the people buy high-deductible, so you have to leave room for consumer choice, there can't be just high-deductible or no-deductible. There has to be much greater variety. So what I expect in the next administration is we'll have broad-based health reform so that people will be able to buy whatever insurance they want under a tax-sheltered umbrella.

One aspect of the high-deductible that hasn't gotten physician attention is that the high-deductible fundamentally changes the behavior of people with chronic diseases. They become much more vigilant about managing their care. Again, the big kahuna is the hospital and the alternative to hospital care, that is, the everything-for-everybody kind of hospitals, are more specialized

systems that focus on diseases and providing everything for that disease, which I think would save hundreds of millions if not tens of billions of dollars. That's the thing that we need to get to.

The other nice public policy surprise is the Romney effort in Massachusetts which is very much like the Swiss system, in which everyone has to be insured. If you can't afford it, [Massachusetts] will subsidize you rather than buy insurance on your behalf. In other words you can be a consumer just like everybody else. Your poverty is not a barrier.

The problem with the Romney plan is that there's only one supermarket and it's the Romney supermarket. Now Romney is a competent person and if you have to have one supermarket, I guess his would be as good as you can get, but why should you have one supermarket? You should be able to shop in many different places for the health insurance you want.

WHLE: Physicians across the country say

“Suppose IBM said, ‘Don’t let Michael Dell be in business, he’s going to hurt me.’ People would find that ludicrous...But somehow that Congress would buy the argument that because specialty hospitals are at least as good and cheaper than the general hospitals, we should bar them from existence is an outrageous argument.”

they are upset about declining incomes and less autonomy. How will they fare in a consumer-directed health care environment?

RH: [Physicians] are the key agent. They have suffered in many ways. They are the key point of service, so when people think about health care, they don't think of hospitals, they think of their physician, their doctor. But because they are so fragmented, they have really very little lobbying power. And the AMA for whatever reason has lost its way as an organization and cannot represent them adequately. In biotechnology the key resource is the scientist – you've got to take good care of your scientists – but these doctors get deprecated and diminished. The whole pay-for-performance movement is not pay-for-performance, it's pay for conformance. Some bureaucrat comes up with some way of treating something and says that if you give a patient an aspirin you're going to get a dollar more. Well the patient might have a blood condition which might make giving them aspirin a disastrous action - how does this bureaucrat know? The doctors' autonomy and ability to practice medicine - in addition to their income - has been seriously compromised.

Right now I have a class of 70 students I would say I have 15 physicians in that class. I'm happy to have them – they're very smart people, but I say what are you doing here? They respond, "Well, I can't practice medicine." So I think what will help the doctors will be consumer-driven health care because they are the valuable resource, and when the consumer will be in charge rather than Congress being in charge, the fragmentation of the doctors and their inability to mount a serious political counteroffensive will be somewhat diminished.

I think the academic community has been terrible to the clinical physician whom they widely depict as a bumbling idiot. Which is ridiculous when you think who becomes a physician - not that they're all wonderful - but if you think about the caliber of person who becomes a physician and the kind of training they go through, to depict them as the village idiot who has to be micro-managed by dictates from Washington, DC is just outrageous. But what the physicians need to help themselves is first consumer-directed health care and the second thing they need is transparency so

that the consumer will be able to see how good the physician is. Not whether he gives you an aspirin, but if I needed breast surgery, how good is this woman at performing that surgery? How many people of my age with my stage of breast cancer has she done surgery on? That level of transparency will be to the physician's benefit.

WHLE: What will accelerate this trend?

RH: The consumer-driven system will absolutely force them. If I had to buy my own health insurance and I were offered alternatives to an everything-for-everybody hospital and let's say I had diabetes, I could go to a diabetes team [that provided all the specialized care] I need. Since the average diabetic expenditure is \$15,000 per person, it's quite feasible to have a system just for diabetics that has a three hundred-bed hospital dialysis center and hundreds of community facilities. If I were offered that, it would surely be cheaper than the present insurance for diabetics and its going to be much better because that's all they do. You know when diabetics need heart surgery, their circulatory system is much different. They require a very different approach than [non-diabetics], so I think the consumer-driven movement will make people focus on the changes in demand. What they don't look at is that these changes in demand will ultimately cause changes in supply. The key element of supply is the management of chronic diseases which is very poorly done and where all the money is. So I believe that that's the critical opening branch and then the consumer will be pitted against the intransigent and manipulative hospital administration system. And that will be a good battle.

WHLE: What other innovations have you been following?

RH: The other thing that's interesting is the concierge medicine movement and it's a physician in Washington state who has a business plan to provide concierge medicine for middle class and lower-middle class people. His brother-in-law is an MBA and a very successful software entrepreneur and they have a model where the physician is levered by a nurse practitioner and you get 24/7 access and the cost is only \$700/year [compared to as much as \$20,000/ year for some elite practices]. That's the kind of market innovation that you expect.

RETAIL-BASED CLINICS: Bringing Efficiencies to Health Care Provision, Finally



JEFF GRUEN is Chief Medical Officer of Revolution Health. Dr. Gruen is a pioneer in the arena of health care consumerism and has had a distinguished career as a senior health care executive for the past 25 years.

At Revolution Health Dr. Gruen is responsible for the health care and clinical direction across the enterprise, and in particular for enhancing relationships with one of the company's key constituents: providers of care. He also manages the company's investment in RediClinic and serves as a member of its board.

Prior to joining Revolution Health he was National Medical Executive at United Health Group, Optum where he helped provide clinical leadership for a \$100 million technology platform project. Dr. Gruen was also Chief Medical Officer for PersonalPath Systems, Inc. where he and his staff helped thousands of severely ill patients dramatically improve their care and outcomes. He was also co-founder of MSO-US, Inc., a company which helped physicians acquire the needed data and skills to coordinate their practices and to best help their patients between visits. MSO-US, Inc. was eventually acquired by a Goldman Sachs-backed company.

Dr. Gruen received his MD degree from Northwestern University and an MBA from Harvard Business School. He completed his internship and residency in Pediatrics at Yale-New Haven Hospital, Yale University.

He served as Director of Pediatrics at a health center associated with The Massachusetts General Hospital. Dr. Gruen has previously served on the clinical faculty of Harvard Medical School and is currently a member of the board of The Disease Management Association of America.

In the American health care system, it is rare for both the patient and the provider to walk away from an encounter satisfied. Consumers complain of scheduling nightmares, long waits in the physician office, and high payments with no price transparency. Providers focus their complaints on decreasing profitability due to high costs, lower reimbursement and increasing bad debt expenses.

The retail-based clinic industry – where patients come on their own schedule, prices are fixed and transparent, and nurse practitioners are the primary providers - is attempting to radically change the way consumers receive routine health care. Has the market finally provided a solution that can satisfy both the provider and the patient?

Several blocks above Times Square in midtown Manhattan, a RediClinic is located in a

Duane Reade pharmacy. Handouts advertise that for \$69, RediClinic offers treatments through a nurse practitioner for 25 common medical conditions such as colds, flu, strep throat, pink eye, stomach ailments and bladder infections. For prices that begin at \$19, the clinic offers diagnostic screenings, vaccinations and immunizations. No appointments are necessary and the usual visit lasts only 15 minutes.

Such clinics are springing up in retail pharmacies across the United States. In a conversation with Jeff Gruen, Chief Medical Officer for Revolution Health - which owns and operates RediClinic - we discussed the growth opportunities for retail-based clinics, the future landscape of the industry, and the advantages retail-based clinics have over traditional physician office

visits.

WHLE: What do you think are the growth opportunities and service areas that RediClinic can provide beyond what they already provide?

JG: The growth opportunities fall in two arenas. The first is to expand the number of convenient care clinics nationwide. It's very hard to determine how large the market for these services could eventually become. Currently there are approximately 200 to 500 clinics.

At the same time, the size of the market for primary care services can be estimated by looking at the number of primary care providers (approximately 100,000 family practitioners, 30,000 pediatricians, and 30,000 obstetricians, adding up to roughly 150,000 practitioners.) We don't see ourselves as a direct competitor, but

actually as a supplement to primary care because of our limited scope of practice and because we are not set up to handle ongoing care. These visits are a minor portion of the primary care slate. With that said assuming the market for convenience services is only 5 % the size of the primary care market, we are still only at 6 % market penetration, so there's a lot of room for growth.

The second arena is chronic disease management, where we can add value in two ways: One, engagement: finding people who would be amenable to disease management and getting them to understand the value of the type of services that can be brought to them. A face-to-face encounter is a wonderful way to get people to really start to appreciate the degree to which they can be helped. Second, direct provision of disease management services – we believe that consumers will actually respond better, be more likely to comply with treatment regimens if they have a face-to-face encounter at least some of the time, and don't just talk to nurses on the phone (as

is the typical disease management model).

WHLE: Convenient care clinics that are staffed by physicians have been around for years. What are the benefits of the nurse practitioner model over the “doc-in-the-box” model that has been around for a while?

JG: The key advantages of retail-based clinics are (1) convenient location, (2) limited scope of practice means wait times are short and predictable, (3) co-location with a pharmacy saves another trip, and (4) lower staffing cost structure translates into lower prices.

Having run a set of centers with the “doc-in-the-box” model, I can tell you that nurse practitioners per se have the advantage of being well suited to a limited scope of practice. Nurse practitioners are very good at being thorough in care for a more limited scope of practice. And

by design and definition we have a substantial limitation on the scope of practice. Interestingly, in my observation, nurse practitioners are ideally suited for this kind of work and one might argue better suited than physicians. So our labor basis is lower with a more predictable and standardized product. And the nurses love it because they have the opportunity to feel like they are making a difference.

Fundamentally, what you are doing is leveraging knowledge assets against the most appropriate tasks. As in many industries where there's been a continual shift in the curve as more highly trained knowledge workers are employed to the most intellectually challenging tasks with the most variation in routine, less knowledge-intensive resources are employed downstream. What you are fundamentally seeing manifest in the convenience care trend is an example of this phenomenon finally become operational on a mass scale in health care service delivery. We are basically making these efficiencies operative in health care

The retail-based clinic industry – where patients come on their own schedule, prices are fixed and transparent, and nurse practitioners are the primary providers - is attempting to radically change the way consumers receive routine health care. Has the market finally provided a solution that can satisfy both the provider and the patient?



where such efficiencies haven't existed before. Of course at the same time, by providing a predictable health care experience within a second consumer routine (the weekly shopping trip) we are solving perhaps the number one problem that consumers have today, shortage of time. I like to think Peter Drucker would be pleased.

WHLE: A landmark event occurred this past summer within the retail-based clinic industry when CVS bought MinuteClinic. Do you see the big retail pharmacies as the industry drivers and do you believe the large scale retail pharmacies are going to buy up the retail-based clinic companies?

JG: It's an open question. The CVS acquisition of MC was clearly an important event, but it is only one data point. It is tough to really determine whether that is a trend,

WHLE: I think the initial perception many people had of retail clinics was that the clinics offer a primary care outlet at a reasonable price to the growing uninsured popula-

tion. In the last six months, RediClinic has signed contracts with UnitedHealthcare, Aetna and Humana to provide insurance reimbursement for RediClinic visits. Who is the targeted patient you are looking for? Are uninsured patients targeted? What are the demographics of these patients?

JG: Our core patient today is the middle income female with children at home. Also a large percent of patients without insurance or a PCP, but this early data may be misleading because we only recently have begun to layer in managed care contracts.]The reality is if you look at current fit, we actually don't have accurate data with regard to insurance status. We are very proud of the managed care contracts we have executed. They are very important large national contracts. Nonetheless, since we don't have 100% penetration of these contracts, it is not actually possible to determine the effect the insurance contracts will have. In addition, there is certainly a Medicare and Medicaid populations out there that are not

being served but these are not currently our focus. It is hard to know actually how many uninsured we're serving. The ideal population has commercial insurance because of lots of factors such as its easier to get the payment and [those patients have] higher utilization. This is not to say we would ever turn away non-insurance.

WHLE: What are the services that the insurance carriers are providing reimbursement for?

JG: Most of the services we offer.

WHLE: One of the greatest benefits of a retail-based clinic is the speed at which you can get in and get out as opposed to making an appointment at a physician office and then being subject to long waits to see the physician during the office visit. Do you see physician offices attempting to become more consumer friendly in response to the growing popularity of retail-based clinics? Will more consumer friendly physician practices represent competition and hinder the growth of retail-based clinics?

JG: We are seeing the stimulation of a welcome consumerization of physician practices. We are seeing physicians extend their hours and increasingly take walk-in patients. There is a trend towards open-access scheduling which allows physicians to take walk-ins while balancing their

load. With that said, there are three reasons why we believe we will continue to grow regardless of physician responses. First, our scope of practice allows us to treat patients much more quickly. We have a work flow process that is ideally suited for rapid turnaround which is not true for physician offices by definition. Second, our co-location with pharmacies gives us an advantage to the consumer that physicians are unable to provide. We are a

one-stop shop for a prescription. Last, we have lower staffing costs which allow us to be price competitive.

We do however see physicians as a strong ally and we believe that we are very good for physician practices. First, we believe that physicians can be very successful without focusing their practices on the routine

visits that are our bread and butter – this frees them up frankly for the higher reimbursement items which require the highest levels of training and skill. Second, we believe in the concept of the Medical Home and find that a surprisingly high number of our visitors don't have a physician – we often are able to make a referral and get the patient plugged into a physician-patient relationship where formerly there was none.

“[W]hat you are doing is leveraging knowledge assets against the most appropriate tasks.... What you are fundamentally seeing manifest in the convenience care trend is an example of this phenomenon finally become operational on a mass scale in health care service delivery.”

Geographic Penetration of Retail-Based Clinics in the United States

Company	Locations In	Locations	States
MinuteClinic	CVS, Target, Cub Foods	162	AZ, CT, FL, GA, IN, KS, MD, MI, MN, MO, NC, NJ, NV, NY, OH, RI, TN, TX, WA
Take Care Health Systems	Walgreens, Eckerd	36	IL, KS, MO, PA
RediClinic	Wal-Mart, Duane Reade, Walgreens	33	AR, GA, NY, OK, TX, VA
The Little Clinic	Kroger, Publix	15	FL, GA, IA, KY, OH

Source: Company websites and press releases as of January 30, 2007.

The Informed Consumer: How Provider Quality and Cost Data Are Reaching the Masses



W H L E E D I T O R I A L

Investors, patient advocates, politicians and health care professionals make strange bedfellows, yet these groups now find themselves rooting for the rise of market-based solutions to health care's ills. In particular, these groups are placing their bets on the power of health care consumerism: the notion that putting consumers in charge of their own health care decisions will improve quality, lower costs, and promote innovations that lead to continuous improvements.

Aetna features on its website a study showing that employers who switch from traditional plans to high-deductible, so-called Consumer Driven Health Care plans, save 10% a year. As evidence like this accumulates, utilization of these plans, which currently cover 3.2 million Americans, should grow in the coming years. The same study found that consumers who subscribe to these plans are more likely to search for information to help them make informed, cost-conscious health care decisions.

When consumers search for this information, however, what do they find? The US health care system is notoriously opaque, with basic information about provider quality and cost difficult to access and even more difficult to use. If you're a consumer in need of a specific procedure, like a coronary artery bypass graft (CABG), it would help to know how many CABG procedures a doctor and a hospital has performed, and what outcomes those patients have experienced. How much will it cost? Try calling a hospital and asking what the total bill for your CABG would be. Hospital charge masters are usually based on arcane multipliers and cross-subsidy economics, making it nearly impossible to get even a ballpark estimate of what it will cost you.

Increasingly, though, a number of organizations are racing to aggregate and organize this data to best enable consumers to make their own health care decisions. The Internet became the obvious portal to this information and since the dot-com boom of the late 1990's, a number of different solutions have entered the market. Most of the companies in this space claim to have been the true pioneer of consumer-driven health care plans, but regardless of who started it, a wide variety of corporations, not-for-profit organizations and even government agencies have begun to make the data available to consumers.

A logical first place to look for these new tools is from the health plans, since they are essentially delegates representing their members and have access to reams of data about them. Indeed, all major health plans have embarked on some platform to help their members become better stewards of their own health. Six years ago, Mike McCallister became CEO of Humana and focused the company on the vision that the consumer should be at "the heart of health care." An example of what emerged is the SmartSuite program, which makes consumers more responsible for the costs of their own health care. Humana found in a three-year study it conducted that SmartSuite customers' health care costs went up 5-6% compared to national averages of 12-14%, and members were more likely to use preventive services to avoid expensive "after-the-fact" interventions.

To help consumers make decisions, Humana created transparency tools that put members in touch with three sources of data about specific hospitals. The first is outcomes data, such as mortality, complication rates, patient volume, and

length of stay. Next is process data: the extent to which a hospital conforms to nationally recognized evidence-based process guidelines. The third piece is structure, which measures hospital compliance with recommendations from the Leapfrog Group, such as whether the hospital uses a computerized physician order entry system.

Members using these tools select hospitals and then get a ranked report based on the data and their preferences, including an estimate of the total costs from each provider with the Humana discount built in. Humana also provides information about physicians, though, as with most other sources available today, the available information speaks more to the convenience of seeing a specific doctor – office hours, addresses with maps and directions – than it does about the physician’s quality. The performance metrics compare a physician’s compliance with nationally recognized process measures to the national averages for process compliance.

Most other major health plans now have similar consumer-driven offerings, either developing them from within or by acquiring start-ups, as UnitedHealth Group did by purchasing Definity in 2004. With a suite of tools organized around the concept, “Activation,” Definity’s vision is to “fully prepar[e] people to take informed action within the health care system,” according to Ian Stanton, Marketing Communications representative for Definity. Stanton says that the key is differentiation, which Definity achieves through services such as sending personalized messages to members to remind them of important health information and phone-based “Health Coaching,” which makes RNs available to help members manage diseases and explore treatment options.

According to Stanton, Definity saves customers 5-12% over traditional plans. Members who read their personal health messages are twice as likely as members of traditional plans to use home delivery for medications, have a 240% higher rate of mammography for women over 50, and save \$52 per member per year.

With the major plans increasingly adding these features, it becomes harder for health plans to differentiate themselves in the marketplace. ConnectYourCare, a Baltimore-based consumer-directed health care platform owned

by Revolution Health, believes that it stands out from its competitors by being “carrier agnostic.” Deborah Godes, Director of the company’s Healthcare Industry Practice, explains, “We aren’t tied a specific health plan. That means that when members change their health plan, none of the data has changed, so ConnectYourCare can migrate with the patient. It doesn’t matter to us whether a member submits a claims fee from Aetna instead of United, because none of the data stored with us has changed.”

Following a very different model for providing health care information to consumers is HealthGrades, a publicly-traded company based in Golden, CO. They have leveraged a rating system for hospitals, physicians and nursing homes into multiple revenue streams. They are most famous for assigning ratings from one to five stars to hospitals. “What HealthGrades does that’s maybe a little bit different from other folks is that we only rate outcomes. We simply look at the track record of the hospital in terms of how their patients fared,” said Scott Shapiro, VP of Corporate Communications and Marketing.

“When HealthGrades first started rating hospitals back in 1998,” Shapiro adds, “it was a very new concept. The whole idea that one hospital was perhaps different than another was totally different.” A lot has changed since that time, when providers were extremely reluctant to encourage performance comparisons. Now, standard-bearers such as the American Hospital Association have publicly embraced physician quality transparency, benefiting organizations such as HealthGrades.

The power of this kind of information can be seen in an example from a physician who preferred to remain anonymous for this article. He said that a patient came to him and asked him to perform surgery, but asked that the physician use a different hospital. The reason was that the hospital the surgeon used most has been rated 1-star for cardiac care by HealthGrades whereas the hospital across town had received three stars. The surgeon had never before been faced with this type of consumer pushback, and it woke him up to the power of consumerism in health care. It also woke up the one-star hospital: after the administration heard the story, it immediately formed a

task force to improve its HealthGrades rating.

For \$17.95, anyone can purchase a HealthGrades report about a specific doctor or hospital, but the bulk of the company's revenue comes from "provider services," which include consulting to hospitals who would like to improve their quality metrics, and licensing the HealthGrades name to providers who would like to advertise their high ratings. Shapiro explains that for the future, HealthGrades is focused on mining the information the website gather about how consumers use information online and what they are looking for. We did a lot of analysis of how consumers use online information and what questions they are asking themselves as they go through that process. "We are going to see some continuous improvement of its information and the way in which it is presented to the consumers," Shapiro said.

Those are the questions that every company in the space is looking to answer, and the stakes could be quite large. According to Prof. Regina Herzlinger, author of *Consumer-Driven Health Care* (see page 24 for the complete Q/A with Professor Herzlinger), the company that does the best job of providing relevant information stands to wield a great deal of power. "It's really thrilling," she said, "that the revolution is going on under the surface and who will become the next vanguard, the next JD Power in this space, that's wide open. That's much better than pay-for-performance."

Outcomes-based quality ratings are better than pay-for-performance, because success is not limited to compliance with tops-down dictates about how to provide care. Pay-for-performance necessarily limits innovation by mandating certain care practices for providers, whereas a focus on outcomes rewards providers who improve the health of their patients regardless of the means.

For the future, the key will be collecting and sharing the critical information consumers need but, for whatever reason, is not yet available. One of the first areas the companies are pursuing is detailed outcome measures for individual physicians. Evidence of improved outcomes from efforts in places like New York State, which required cardiac surgeons to publicly share their performance data, is paving the way for new

approaches from both the public and private sectors. ConnectYourCare, for example, hopes to add a powerful new physician quality-assessment tool in 2007, and many others are working along similar lines.

A persistent problem with available information is understanding the actual costs of a given procedure. Most of the resources described in this article can provide an estimate, but no one can give you an actual quote until after you've already incurred care. Tip Kim, head of L.E.K. Consulting's West Coast health care practice explains why this is so complicated: "If you go to a hotel room, and you look at the back of the door next to the fire exit diagram, there is what's known as a rack rate in a hotel room. The number on the back of the door is a completely meaningless number. But because of the discounts, because of the occupancy, depending on what group rate you got, what corporate discounts you got, the number that you actually pay has nothing really to do with that rack rate. That magnified and multiplied many-fold is what the health care system is like."

Another major problem is that people treat health care decisions very differently than they do other products or services. When you buy a DVD player, for example, the worst-case scenario is that it doesn't work and you're out a hundred dollars. But with health care, the downside is catastrophic, and people will pay what they have to - often well beyond their means, when you consider the number of bankruptcies last year caused by health care costs - that the decision is far more scary than the purchases consumers make on a daily basis.

To help people with these decisions, Kim imagines a website with actuarial tools where, "you basically go in and say, here is how many family members I have, here is how many doctors visits I have had, here is what chronic conditions I have had, and then compares what you would pay out of pocket for an HMO, what you would pay for a PPO, what you would have paid out of pocket if you were healthy, then for an HSA, for a high deductible plan. It actually does all the math for you and makes it much easier. Now all you are choosing between is what kind of risk-taker am I? How reasonably assured am I that I'm going to be healthy? Right now you have to do that assessment, plus you have to do all the math."

AQUI(RED) DESI(RED) PREPA(RED) (RED)UCE

Global Health:

ADMI(RED) HI(RED) PROCU(RED) REQUI(RED)

Creative Partnerships

ADO(RED) INC(RED)IBLE (RED)EFINE SAC(RED)

to Conquer

ASSU(RED) INSPI(RED) (RED)ESIGN SHA(RED)

AIDS in Africa

CULTU(RED) PARTNE(RED) (RED)IRECT WI(RED)

With a \$30 billion shot of cash granted to the Gates Foundation from Warren Buffett, the year 2006 ended auspiciously for global health and education. Suddenly, the responsibility to better global health wasn't limited to the usual suspects, and expanded to include private companies and iconic global brands. **DEAN CRUTCHFIELD**, of Wolff Olins, talks about **PRODUCT (RED)™**, and how brands can generate sustainable funding and improvements in global health. **DR. ERNEST DARKOH**, of BroadReach Healthcare, discusses what makes public-private partnerships succeed, and describes his efforts in building scalable AIDS treatment delivery models in Botswana and improving provider access in South Africa.

PRODUCT (RED)TM: A New Business Model for Global Health Philanthropy



DEAN CRUTCHFIELD is the Executive Vice President, Marketing for Wolff Olins. Dean has over 20 years of marketing and branding experience working with some of the world's most recognized brand consultancies and has worked on a wide spectrum of corporate, retail and consumer brands internationally. With a love for brands, he has spoken around the world, espousing on the value of brands for well-known institutions, and published articles on the power of branding and the convergence of new media in BrandWeek, MediaWeek and AdWeek.

Here, Dean describes the unique journey His company took to help Bono and Bobby Shriver launch PRODUCT (RED). PRODUCT (RED) has formed partnerships between iconic world brands and the cause to fight against AIDS. These partner brands produce goods and services, and contribute some of their profits to the Global Fund.

Dean stresses the need to use creativity and innovation to push boundaries and bust categories with brave thinking to create new and better ways for brands that can help build a better world.

WHLE: Take me back to the beginning when you were first approached by Bobby Shriver and Bono. What were their objectives?

DC: In its infancy, the main task was an idea and vision by Bono: create a brand that brought idealism and pragmatism together. This brand needed to support a huge cause — to eliminate AIDS in Africa (working with the Global Fund to Fight AIDS, Malaria and Tuberculosis) — and Wolff Olins needed to create a brand that would entice customers to vote and voice support with their wallets.

In the spring of 2005, we were asked to pitch our ideas to Bobby Shriver and in January 2006, Bono presented PRODUCT (RED) at the World Economic Forum with the AMEX RED card. To create PRODUCT (RED), we started out by defining the opportunity, looking at the issue and today's crowded space of philanthropy - what's missing for customers and what's special about

RED - and thinking about what the brand would achieve. We also wanted to find and develop the best business model for a brand that would take AIDS in Africa to the "high street" in America.

By the summer of 2006, while working closely with the RED team, we figured out the multi-tiered strategy for the new partner brands that would inevitably join. American Express, GAP, Converse, and Armani were already founding partners, but when PRODUCT (RED) launched with the (RED) American Express card in the UK, Motorola also became interested, and joined as another founding partner – a very exciting day, as I recall.

WHLE: Tell us about the PRODUCT (RED) launch? What did you learn?

DC: We launched in the UK as a test market to prepare for the US market. By March 2006, the UK launch revealed, in an independent study, that 30% of representative respondents had a more

positive opinion of the brands involved because of their involvement with PRODUCT (RED). For example, American Express, in the UK at the time, wasn't as highly regarded as it is in the US - in fact, it was considered one of the top 10 "evil" brands in the UK, so to see such a positive upswing in perception was not only impressive, it was good for business.

The launch was undeniably a successful start for PRODUCT (RED). We saw a strong uptake of people requesting the product, media attention, the groundswell as word of mouth spread, and the enhancement of the partner brands' reputations.

However, the US is the most important market for the success of PRODUCT (RED) and its sustainability. For when it comes to philanthropy, 15% of the US's GDP is linked to non-profit. There's nothing like it in Europe or elsewhere in the world: it's an amazing country with an appetite for philanthropy and non-profit.

When the US launch happened in December 2006, we had these great, venerable brands that took part in the program. The level of involvement and investment was significant: they each took a primary role and did something extraordinary using their brand for PRODUCT

(RED). For example, GAP expressed (RED) through a distinctive range of clothing, Converse created a specific range of shoes, Armani and Apple examined their products to see how they could match their brands with PRODUCT (RED) and Motorola designed the RED Razr, with its own features and interface.

WHLE: It's a crowded market of fiercely competing brands. How is PRODUCT (RED) different?

DC: The launch of PRODUCT (RED) challenges the norm for how we could see tomorrow's philanthropy. It is an excellent example that

throws the arena wide open for initiatives and charity. You're bringing together a unique initiative that binds virtue with desire.

These days, it is hard to just be guilted into giving charity. You know how it happens: you see photos of starving children or photos of horror. I am not criticizing this approach. It's just the norm of charity advertising. PRODUCT (RED), however, seeks to do something different. It seeks to appeal to a consumer's aspirations. To me, the world of brands and consumers is an incredible world. Consumers have desires to buy cool products by great brands, and to add virtue to that brand is a new level. In this case, it was a

collaborative effort of truly great products for a virtuous purpose — the emotional appeal of these brands and products warrant a purchase to get involved.

WHLE: Did you set any success metrics? What success have you achieved since the launch?

DC: There were no preconceived ideas on the return on investment or prescriptive measurement tools set for the launch of PRODUCT (RED). We were playing a different role here to make something that goes against the grain. To be successful, we needed an emotional appeal...we needed to

stand for something unique...and we needed to say something through our brand partners using a movement, a brand and an attitude.

The results were impressive: in May 2006, \$1.25 million of the first PRODUCT (RED) money received by the Global Fund flowed to Rwanda. The money went towards the Rwandan Ministry of Health's comprehensive HIV/AIDS program to provide anti-retroviral treatments for children and adults in a third of the country. During the week of September 11, 2006, \$4 million of PRODUCT (RED) money flowed to Swaziland. The money went to feeding, educating,

"During the week of September 11, 2006, \$4 million of PRODUCT (RED) money flowed to Swaziland. The money went to feeding, educating, and protecting orphans; and supporting patients on anti-retroviral therapy. On September 19, an additional \$5 million was disbursed to Rwanda to support the national prevention and treatment programs."

and protecting orphans; and supporting patients on anti-retroviral therapy. On September 19, an additional \$5 million was disbursed to Rwanda to support the national prevention and treatment programs.

WHLE: PRODUCT (RED) is described as being between the world of philanthropy and commerce (less a campaign, more a business; less a charity, more a choice; more value, less ethical belief). Tell us more about this.

DC: PRODUCT (RED) is about conscious commerce. What's interesting is that whilst eliminating AIDS in Africa is the goal, for brands, RED is *also* a brand that can help leverage top-line and bottom-line growth for the partner brands, and enhancing reputation can contribute to that. This is not about cutting a check to charity. It's the [participating] brand to the power of RED: it's part of the participating company's portfolio, and it derives economic benefit, but only if a company has dedicated a genuine and credible part of its revenue to the cause.

Of course, with more of a business orientation, there is suspicion as to how much money actually goes to the cause. When you are dealing with philanthropy, there has to be truth and integrity. If the business is looking at this to purely build revenue, then that is tantamount to failure. Of course, these are all the realities of business. To be a part of PRODUCT (RED), there must be reputation and commercial benefit, but companies can't just join purely for commercial reasons. Consumers are already skeptical as it is.

In short, there are two circles overlapping here: one of philanthropy, and one of customers. The consumers are asking: "How do I get something in return for contributing my money?" Today, brands have a massive role in society, and they are in a position to build a better world...to change the world. Some people trust certain brands even more than their government.

This is not about the brands of yesterday, like a brand image that is tightly controlled and driven by "Cokes" of the world. Today, brands are owned by the consumer. It is more of a participatory and democratic experience. Today, brands are about how they inject themselves in society, and in this case, in a movement to force philanthropy into a different light.



Many think that brands primarily express what you are or what you own. But, there is also part of a brand that communicates who you are. Some brands represent a lifestyle and what you have, while others exhibit who you are and what you believe. With PRODUCT (RED), you can vote with your wallet, buy something cool and take part of something larger. You can communicate something to others about what you believe in. At its core, it is about the brand and beliefs, not the charity. It is not about being guilted into giving: it is about positively affirming a cause through your buying power.

WHLE: Are other companies interested in joining PRODUCT (RED)?

DC: After the launch in the US, PRODUCT (RED) was getting three calls every 15 minutes from big brands who wanted to get involved. Some may see it as low overhead and an opportunity to make commercial gain, but the RED team challenges all the companies to explain why they want to get involved. If it's for commercial gain, it's not right for RED and they will not work with them. If it is in line with a genuine philanthropic strategy that fits with PRODUCT (RED), if the brand is prepared to do something extraordinary with PRODUCT (RED), then serious discussions will be held. At this point, it's about sorting out the wheat from the chaff, and evaluating new ideas offered by potential partners.

As long as there is truth and integrity in the partnership, and clear expected revenue shares, the deal will make sense, and they will add new partners. There are also different levels of involvement: some give payment in kind (e.g., MTV and Oprah gave free media coverage), and some are full partners (e.g., creating a new product) who help shape the future of PRODUCT (RED).

WHLE: Do you think this market will become saturated?

DC: We're planning on building out the program. Motorola and American Express have not yet launched in the US, and I think it will be huge. We have experienced an amazing groundswell. But, with expansion and growth we have to consider the sustainability of PRODUCT (RED).

With this kind of progressive and participatory brand, we need to protect PRODUCT (RED) from the companies that don't get involved in a truthful and ethical manner.

Many talk about the future of philanthropy as "social entrepreneurship" or "philanthrocapitalism," but for me, it is about big brands trying to build a better world through their success. It would be sad to see this become tainted, or if we lose the sophisticated consumer because the brand or main message is drowned out by too many companies getting involved in it.

Today, charity is a world deluged by people doing different things. Today, you see a big driver in global health fund-raising as a cult of celebrity that promotes social entrepreneurship. However, it may not be sustainable in the long run. My hope is that because PRODUCT (RED) is intrinsically linked to business — we can shift the paradigm of how we currently view philanthropy. We begin to see it as not separate to the business, but core to the business.

WHLE: Will PRODUCT (RED) be launched globally?

DC: Yes, Japan is next. Are there limitations to PRODUCT (RED)? First, it cannot be all things to all brands, to all consumers. Also, there are so many exciting brands, and so many things they could be doing. We don't have all the answer now. Today, PRODUCT (RED) is a fluid brand, and of the moment.

As we launch PRODUCT (RED) in other

countries, we struggle with the main concern: although more people may mean more stability and sustainability, how do you maintain the integrity and authenticity? I think the key is not to be greedy. We need to define strict lines of engagement when considering partners, and to only

accept exceptional ideas or initiatives. This forces potential partners to think long and hard about how they can contribute something that they have never done before.

WHLE: What are the future prospects for PRODUCT (RED)? What will it look like in five years? What are the challenges?

DC: In the coming years, I see PRODUCT (RED) as a truly global brand with more partners.

Our challenges: Can we maintain its freshness? Can we maintain its momentum? Sometimes the best way to keep it alive is to constantly involve new partners locally and globally. This won't be about saturating the U.S. market with 100 partners. If we don't like change, we will like irrelevance even less.

Can we really expand globally? Most importantly, we need to get the U.S. market right first. As with anything, the first generation will have some bugs, but the next ones will be better. So far, PRODUCT (RED) has organized in an amazing way, but we will face growing pains as we expand. How do you make decision as a small group vs. a larger group? What are the rules of engagement?

Can we maintain the believability? It's a brand and a cause. Will there be moments where it may be tarnished by actions by partner brands? These are risks we take. There are also lots of opportunities: this is the first time brands have partnered in a unique way to give back.

One thing will be constant: PRODUCT (RED) will continue to support Global Fund for many years. It has a great track record, and it is a highly regarded organization that isn't open to individual contribution and avoids preferential treatment.

"My hope is that PRODUCT(RED) is linked to business, we can shift the paradigm of how we currently view philanthropy. We begin to see it as not separate to the business, but core to the business."

CONVERGING FORCES: The Future of Public-Private Partnerships



ERNEST DARKOH, MD, MPH, MBA is an internationally recognized expert in global health program management, strategic planning, health systems development, and large-scale treatment program implementation. He is widely acclaimed for his bold leadership in helping develop and manage Botswana's National Antiretroviral Treatment Program (Masa), one of the largest public sector HIV/AIDS treatment initiatives in Africa and a program widely regarded as a "proof of concept" model for large scale antiretroviral therapy. As Chairman of BroadReach, Ernest provides leadership to the development, implementation, and management of the company's innovative portfolio of global health projects.

In 2005, Ernest was named one of 18 "Global Health Heroes" by TIME Magazine, and been named a Young Global Leader by the World Economic Forum. Previously, he served as a management consultant for McKinsey & Company in New York and South Africa.

Ernest holds an MD from Harvard Medical School, an MPH from Harvard School of Public Health, and an MBA from the Said School of Business at the University of Oxford, England as a Fulbright Scholar.

Here, Ernest speaks about key success factors to implementing large-scale public health change in Botswana and South Africa, and discusses the future of public-private partnership.

WHLE: You've achieved great success with the Merck-Gates Foundation HIV initiative in Botswana. What key factors drove your success?

ED: The first thing was that it was well planned, very well thought through, and very well put together. It had a sound strategy and approach, which was, instead of distributing \$1.5 billion on lots of countries, it focused on one country, where we could show tangible benefits. We also set forth an agreement that set up a culture to make sure that we had joint decision-making on the public *and* private sides.

In addition, another success factor was the excellent leadership of the Botswana government. The government was very forthcoming in acknowledging that they needed private involvement. I find there are a lot of instances where the private partner tries to convince the govern-

ment, and the government doesn't respond well. This was an occasion where the government of Botswana reached out and said, "Look, we know that we have needs for skill sets that don't typically sit in the public sector." HIV in Botswana required more than just the typical public sector approach. They deliberately and consciously reached out to a private sector partner who had the skills, capabilities, know-how, and network.

Third, we created a real public-private partnership team. At the time, I was seconded into the Ministry of Health as a civil servant in the government of Botswana. They gave me that designation so I could sit on the team, and work within the government. A lot of typical public-private partnerships I see have the private team sitting outside the government, or the public side sitting outside of the partnership. This team was a true joint team where myself, and a few other key experts — people from private sector marketing,

health education, behavioral change, organization, IT consulting — worked closely together. It was a true public-private partnership in its foundation, its structure, and its operations.

I believe those three elements were key to our success in functioning as a true public-private partnership.

WHLE: Why did you leave?

ED: I left the project in March, 2005. At that point, in my role as Operations Manager, I completed my mandate of rolling out the treatment program. One of the key principles we instituted was: “Don’t outlast your usefulness.” Our role was to do the job, not keep the job.

Today, they have their own staff of two full-time people who run the program. One thing to keep in mind is that the Gates Initiative was a holistic HIV-AIDS effort, including prevention, treatment, care, etc. My role was one particular project within it, and there were other managers that led prevention and care.

The overall project leader is still on the ground, head of the Athens HIV Partnership; I reported to that person, and the Deputy Secretary at the Ministry of Health.

WHLE: Are there any other challenges that the team faces today?

ED: I’ve kept in touch with the team until late last year. The challenges that they face are challenges that we predicted we would face. There wasn’t anything that was truly surprising.

The key challenges that the team faces are: one, providing adequate levels of follow-up to HIV patients. Early in the program, we discovered that when you’re talking about treating HIV, you’re talking about how to manage the most

“well people.” I think when people hear about HIV or AIDS patients, in their minds, they think of people who are bed-ridden or in the wards. That’s the minority. At any given moment, there’s only a small proportion who have reached that level of severity, and require intensive care.

The reality is that the bulk of people who are infected, even those who qualify for therapy, don’t have an agent for health care. HIV is often their first illness, and drives them to have their

first interaction with the health system. If you find someone critically ill and treat them, they become functionally well. In other words, if you’re on treatment, you can do anything anyone else can do. For the most part, the population who receive treatment consist of well people, who don’t spend their time in hospitals or clinics. They spend their time working and living normal lives in the community.

Second, we need to build systems that manage the follow-up and compliance process. We need an effective community-based system to monitor HIV like a chronic

disease, like how one would manage diabetes. One of the things that was unique in Botswana was the level to which civil society had developed a structure that had capacity to manage large numbers of people in need of a particular service. I think this the way Botswana was: the government had always taken care of its people, and as a result, there was a lack of community-based institutions that grew up to meet growing health care needs. Now, the burden of treating HIV is so heavy that it requires community-based institutions to rise up to meet some of the capacity.

So, that’s one of the key challenges: building a system that enables health care workers to follow up with patients, make sure that they’re

"The reality is that the bulk of people who are infected, even those who qualify for therapy, don't have an agent for health care. HIV is often their first illness, and drives them to have their first interaction with the health system. For the most part, the population who receive treatment consist of well people, who don't spend their time in hospitals or clinics. They spend their time working and living normal lives in the community."

taking the medication as they should, identify problems early, and be able to get patients back to the health care system before they become catastrophic.

Along with that challenge is the ability to roll out treatment at the local community clinic level, not just at hospitals. Hospitals have limited clinicians, and people have to travel far to get to one. People should be able to go to their nearest local clinic. Most local clinics don't have doctors, and many don't have the training to do full care for patients. At this level, obviously, it's easier said than done. What is needed is a system that empowers them to improve capacity and manage more than they normally manage. Building models that empowers first-line treatment — that's a big change in policy that requires courage and perseverance to accomplish.

Third, we need to manage resistance — and it will develop, even at the best treatment programs. The treatment for HIV is getting more complex, and requires more expertise. As the tests get more expensive and depend on being centralized, the need to implement a resistance strategy at the community-based level becomes more critical.

Fourth, frankly, is the challenge of managing the quality of care. So, you're not going to get health workers, oftentimes in the country with no electricity, to use computers. All we can do is create good paper-based systems: get the clinics the paper to record data, find a way to digitize it, take the data and analyze it, then give that colleague the data to improve delivery. For example: "These are the people whose viral loads are still detectable." Typically, when a site sees thousands of patients, there are going to be thousands of paper-based records. There's an army of available data: imagine if someone could photocopy the record, go into the nearest place in town and fax the record to a central location, and the numbers are crunched centrally and an algorithm is applied to determine a recommendation. Then, feed the recommendation back to the site.

This is the sort of model that they need to develop. To give you an example, in our program in South Africa, we've applied creative models of telemedicine and technology to monitor for quality of care. For instance, if you have a doctor

who shows consistent underperformance in liver function tests, you can now intervene by doctor and say, "Hmm...that person needs a little more training." We've tried to be very practical and use technology where it makes sense, because it offers us so much more in efficiency that we couldn't do before.

How does telemedicine work? One specialist doctor who lives in Capetown can supervise hundreds of doctors in the field to provide treatment, whereas before, they weren't able to provide it. Using the telephone, paper or fax machine, they can monitor quality and provide real-time learning as well.

One final challenge I know Botswana faced, and other countries face as well: laboratory logistics. To test a viral load is a complex process that requires highly trained workers and can only be performed in relatively large hospitals. The logistics to shuffling samples back and forth in a timely manner can be daunting. The one thing companies can do is to explore simpler technologies (e.g., small machines that can be used in rural areas to draw blood, test it for HIV, and get instantaneous results).

WHLE: Describe your current work in South Africa.

ED: In South Africa, the program is functionally different from the work in Botswana. The South Africa program is a public-public partnership, funded by a US government grant, and we're one of the implementing agencies on the ground.

What we're doing in South Africa is partnering with each province to help government hospitals fill their capacity so they can provide the enrollment levels necessary to meet their targets. Our secondary goal is to mobilize the private sector in South Africa in places where the government is slow or experiencing different constraints. Using our network of private providers, we can keep people alive while the government capacity is set up. We're using the telemedicine model whereby 4,000 doctors: we can augment capacity and "activate" a provider to take over the care of a patient, identified by the government on a case-by-case basis.

I believe this is a cutting-edge model: using telemedicine to monitor quality, having good tracking abilities through electronic records

(despite the fact that records are currently all paper-based). The ability to analyze data and relay actions to improve care is critical work, but not work that has to be done at the local sites. They're often understaffed, and with this model, we can provide a critical stop-gap service and use a technology that is more appropriate. You really take the approach where you work with the government and in-house resources, from HR to labs to IT to patient education, to improve patient flow.

The second goal to mobilize the private sector: once we activate a provider, the patients don't worry about paying when they show up at our provider. It's like a Medicare program for HIV. Any province can contact us, and say, "Look, we're stuck here, we need your help with these patients to stabilize them before they become critical."

WHLE: What is the future of the public-private partnership?

ED: I'm a firm believer that public-private partnerships are the model going forward. Neither private or public sectors have the capacity or the know-how to attack some of these problems individually. Some corporations write a check to fund a program or buy a few meals. I believe corporate social responsibility can evolve to asking: How can companies provide a meaningful contribution to the Botswana government to roll out the AIDS program? For example, think about HIV marketing. How do you convince people to use condoms? I would ask a company whose employees are skilled at convincing millions of people to buy their products through creative marketing. Many people in the public sector have never sold anything in their lives.

Second, public-private partnerships need to go beyond the realm of philanthropy to the realm of bottom-line profits. For the CEO of a company, he or she has a bottom-line responsibility, and that should include looking at Africa as a market opportunity, and undertake efforts to activate the market and create jobs. Instead of just making a

donation, let's talk about providing real resources to bottom-line initiatives to establish factories, build production capacity, drive the economy, develop markets, and raise purchasing power.

My vision of public-private partnerships is a very practical, "nuts-and-bolts" approach to build capability, not just goodwill. Goodwill is great, and we need that, and I'm not advocating that we

stop that at all. But I think that companies should ask themselves: if we have the capability, why don't we get truly active and develop a market? In the US, they didn't build their economy based on the non-for-profit model. So, why would we use the same model in Africa? It makes no sense to implement here, especially when you're relegating a conti-

ment to being beggars of the world.

Private corporations should at partnering on turnkey projects with government. We're not going to do this on a donation model. I believe there's a phenomenal market opportunity for hard core businesses, and yes, it requires a lot of work to establish a foundation. That said, it's a great market for first movers.

Third, I think public-private partnerships are about management. Ideas can be great, but are only as good as their implementation. An okay idea implemented by a good manager will yield better results than a great idea implemented by a poor manager. One of the things you see in Africa that makes it a difficult environment to work in is poor management. In particular, even in developed countries, management is unappreciated in health care. How do you manage a budget? How do you forecast and project revenues? How do you best allocate your resources?

To me, public-private partnerships work because countries can benefit from the private sector management expertise that isn't traditionally embedded in the public sector today. By bringing these skill sets and people together, it results in a yin-yang relationship. If we can manage these partnerships and set them up in a fundamentally sound manner, I think we can accomplish a lot more than we are at the moment.

"But I think that companies should ask themselves: If we have the capability, why don't we get truly active and develop the market?"

Footnotes for Medical Tourism: All Things Equal, I'd Rather Be In Bangkok (page 20)

¹ Tatko-Peterson, Ann (2006). Going Abroad for Health Care: Medical Tourism Heads Towards Robust Industry. *San Jose Mercury News* (October 16, 2006).

² Lancaster, John (2004). Surgeries, Side Trips for 'Medical Tourists: Affordable Care at India's Private Hospitals Draws Growing Number of Foreigners. *Washington Post Foreign Service*, page A01 (October 21, 2004).

³ Badam, Talwar (2005). Westerners Seek Inexpensive Medical Care in Asia. *Associated Press* (September 25, 2005).

⁴ Ibid, pg. 359

⁵ Hutchinson (2005). Medical Tourism Growing Worldwide. *UDaily, University of Delaware* (July 25, 2005).

⁶ Advisory Board Company Staff (2005). International patients, part 2: U.S. hospitals developing overseas presence through consulting (May 14, 2005).

⁷ Business Day staff (2006). Thailand's Private Hospitals Prepare for Overseas Push. *Business Day* Page 5 (April 27, 2006). Retrieved from <http://www.bumrungrad.com/htm/eng/press/article.asp>

⁸ Retrieved from <http://www.jointcommissioninternational.org/international.asp?durki=8069>, on October 27, 2006.

⁹ Nazir, Zeenat (2006). Just What the Hospital Ordered: Global Accreditations. *The Indian Express* (September 18, 2006).

¹⁰ ibid

¹¹ Retrieved from <http://www.medretreat.com> on October 15, 2006.

¹² Retrieved from <http://www.planethospital.com> on October 20, 2006.

¹³ Appleby, Schmit, "Sending Patients Packing," *USA TODAY* (July 27, 2006).

¹⁴ Bethely, "North Carolina Company Drops Plan for Overseas Care," *AMNews*. (October 23, 2006).

¹⁵ Skidmore, Sarah (2005). Cross-border health insurance is a hit with employers and workers. *Union Tribune* (October 16, 2005).

¹⁶ Geis, Sonya (2005). Passport to Health Care At Lower Cost to Patient: California HMOs Send Some Enrollees to Mexico. *Washington Post* (November 6, 2005; Page A03).

¹⁷ Bill to amend the Code of West Virginia, designated §5-16-28

¹⁸ ibid

¹⁹ http://www.webmd.com/hw/heart_disease/aa68137.asp

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