

Healthcare Reform Phase II: An Opportunity to Lead A Healthcare Industrial Revolution

2010 OUTLOOK ON HEALTHCARE ECONOMICS & INNOVATION

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EDITOR'S NOTE: This paper is the second "Annual Outlook" published by healthcare venture capital firm Psilos Group. Since 1998, Psilos has fueled the development of 38 companies, driving healthcare innovations that reduce cost, improve quality and align incentives across payers, providers and patients. The firm's team has 140+ years combined experience in healthcare management and investing, specializing in healthcare innovation and healthcare economics. The Psilos Annual Outlook is intended to provide investors, analysts, businesses and policy-makers with a guide to the issues and trends that will shape healthcare growth investing in 2010 and beyond.

Healthcare reform has finally made its way through the U.S. political machinery, emerging on the other side as a \$1 trillion reform plan that extends health insurance to 32 million additional Americans and eliminates other barriers to healthcare insurance. This law remains the subject of great debate, primarily because it has ignited a dramatic conflict around the economics of healthcare.

The final healthcare reform law, known formally as the Patient Protection and Affordable Care Act (PPACA), focuses primarily on healthcare access and insurance reforms. It does very little to address the underlying costs and structural issues that have driven healthcare costs to inflate at a rate of two to three times the national inflation rate. Adding 32 million people to those bad economics will place additional stress on a healthcare system that was already on pace to grow from 17.3 percent of GDP in 2009 to more than 19.3 percent of GDP by 2019¹.

While the long-term fiscal implications of PPACA are worrisome, businesses and government cannot hide from the change that is coming. A positive effect of this law will be to accelerate the importance of catalyzing healthcare innovation that improves quality and reduces cost. If companies are going to survive and prosper, they need to nurture the development of a new healthcare economy that focuses on delivery of true value for every dollar spent.

This is easier said than done. And yet failure will lead an existing \$2.5 trillion industry to inflate to over \$4.5 trillion in 2019², according to CMS, and further weaken our overall economy. Establishment of a successful new healthcare economy will require a virtual "industrial revolution" in our field, born from the adoption of new approaches in all corners of the healthcare system. Among the areas needing the most attention, and which can produce the largest results are:

¹ "Recession Expected to Impact Growth in National Health Expenditures Over The Next Several Years". Centers for Medicare and Medicaid Services. 4 Feb. 2010. <<http://www3.cms.gov/apps/media/press/factsheet.asp?Counter=3582&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date>>

² "National Health Expenditures Projections 2009-2019". Centers for Medicare & Medicaid Services. 4 Feb. 2010. <<http://www2.cms.gov/NationalHealthExpendData/downloads/proj2009.pdf>>

- Creation of new payment and delivery systems
- Development of new models of insurance
- Dramatic improvements and reduction in administrative costs
- Elimination of costly errors and ineffective treatment modalities
- Reduction of unnecessary hospitalization through intelligent use of technology
- Deployment of diagnostic and treatment tools that enable better outcomes at lower cost

Transformative change in our healthcare system is required, and this can only be achieved through innovation and the adoption of new ideas. We cannot simply go on investing in incremental changes to approaches that have failed repeatedly such as: classic disease management, standard insurance models and traditional fee-for-service medicine. If done well, these disruptive models of healthcare services and new medical technologies will be the foundation for opportunities to create new businesses based on 21st century technology. Such a healthcare industrial revolution would go a long way towards eliminating the 30 percent waste and error characteristic of our current system, improving our national competitiveness and creating new products for global exportation. This is not a new story. Rather it is the story of America's history, which is one of solving serious problems and renewing the country through industrial innovation and public/private partnerships that foster growth. Absent healthcare innovation we may find that our only alternative would be the implementation of a single payer system, and that also is not a solution. Every country that has adopted a single-payer approach is experiencing healthcare inflation similar to or greater than what we are contending with here in America, while at the same time lagging behind other parts of the world in fostering innovation.

Achieving this healthcare revolution will require serious consumer engagement and a real partnership between business and government. It will also require an end to the acrimonious debate recently experienced over healthcare reform. There are no devils in healthcare, only worn out broken systems. The return for the U.S. in accomplishing meaningful healthcare reform will be a vibrant healthcare economy that enhances the public good and private enterprise at the same time.

Healthcare's problems are so big that they cannot be solved with one or two fragmented ideas. Rather, it is a series of huge and complex problems that need to be attacked on multiple fronts. As a start towards engendering a meaningful discussion around the topic, we offer here six specific recommendations to create near term, high impact and high return changes to improve our healthcare system. We recognize that this is not an all-inclusive list and that there are other areas, especially around regulation, tort reform and licensing, even food and agricultural policy, which can add fuel to the fire of healthcare revolution. However, we believe these are specific core areas of opportunity that will create a meaningful and long-lasting return on investment:

I. An efficient system to prevent and manage with chronic illness

Chronic illness accounts for 78 percent of all of our healthcare expenses³ and our population is aging, amplifying the problem for years to come. In 2000, an estimated 57 million Americans had multiple chronic conditions, and the number is projected to increase to 81 million by 2020.

³ "Chronic Illness and Disease Management: House Joint Resolution 10 Task Force Key Findings and Recommendations". Delaware Healthcare Commission. June 2004. <<http://dhss.delaware.gov/dhss/dhcc/files/chronicillnessreportfinal0804.pdf>>

Medicare beneficiaries who have two or more chronic conditions represent 65% of Medicare beneficiaries but generate 95% of all Medicare spending⁴. Analysts and economists agree--without greater efficiencies in the delivery of care to these beneficiaries, the trust fund that finances Medicare Part A is projected to be insolvent in 2017⁵. To deal with this, we must:

- A. Prevent avoidable hospitalizations and re-hospitalizations, which cost the nation in excess of \$30 billion annually⁶, by using new technologies aimed at improving care management of the chronically ill and improving transitions from inpatient care to the home.
- B. Incentivize the under 65 population of the country to live healthier life styles through use of prevention and wellness tools. The best approaches encourage people to prevent and manage illness early on through education, insurance benefit design and financial incentives. This approach is now a regular feature of healthcare programs in several EU countries, such as Holland and Switzerland and it is starting to take off in the U.S. as well. Wellness and prevention must be made to play a role in reducing chronic illness, as we currently rank 49th in life expectancy and number 1 in healthcare costs⁷

There are numerous ways in which these ideas translate into business opportunities, including:

- Value-based health plans that integrate wellness and prevention incentives
- Consumer engagement tools that give the patient the means and motivation to engage in preventative health behaviors
- Accountable Care Organizations and other new models of healthcare service delivery that will require virtual system integration of clinical, care and enterprise management
- Software and services that enable “pay-for-performance” models that reward providers for improving health outcomes
- Telemedicine and remote monitoring technologies to use in treating chronically ill patients and to help manage transitions from the hospital setting

Companies commercializing products around each of these opportunities already exist, albeit in nascent form, and are demonstrating promising results.

II. Error reduction in inpatient, ambulatory, and post-acute care

It is generally acknowledged that the U.S. healthcare system is riddled with excess costs due to avoidable medical errors. These errors are most often caused by poor information flow and imperfect human behavior.

⁴ Wolff JL, B Starfield, Anderson G. Prevalence. “Expenditures and Complications of Multiple Chronic Conditions in The Elderly”. Arch InternMed (2002).
“The Co-occurrence of Chronic Diseases and Geriatric Syndromes: The Health and Retirement Study”. Journal of the American Geriatrics Society 57.3 (2008).

⁵ “2009 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds”. The National Consumer Protection Technical Resource Center. <<http://www.smpresource.org/Content/NavigationMenu/HealthCareFraud/Medicare/MedicareTrusteesReport09.pdf>>

⁶ “National Healthcare Quality Report, 2008”. Agency for Healthcare Research and Quality. <<http://www.ahrq.gov/qual/nhqr08/Key.htm>>

⁷ “Country Comparison: Life Expectancy At Birth”. The World Factbook. Central Intelligence Agency. <<https://www.cia.gov/library/publications/the-world-factbook/rankorder/2102rank.html>>;
Ritholtz, Barry, “Health Care Expenses vs. Life Expectancy,” The Big Picture (2010). <<http://www.ritholtz.com/blog/2010/03/health-care-expenses-vs-life-expectancy/>>

Poor flow of information leads to mistakes of both commission and omission in the delivery of care and occurs in multiple areas when providers are unable to get a full clinical picture of a patient, including:

- Within facilities such as hospitals and post-acute care settings
- From facility-to-facility or from facility-to-physician upon discharge.
- Between patient-to-provider

The business opportunities created by improving information flow to reduce the prevalence of clinical errors include:

- A. Transportable personal health records that follow patients throughout their lives and which provide a two-way (provider-to-patient and patient-to-provider) means of communicating about patient health
- B. Evidence-based clinical search engines and similar tools that use patient data as an input and provide highly customized best practice alternatives to care providers at the point-of-care
- C. Secure systems that enable patients' confidential information (with patient consent), to be transmitted from facility-to-facility and between inpatient and outpatient providers

Technology is also the solution to medical mistakes caused by human error. Too often caregivers fail to adhere to well-established evidence-based protocols and perform their clinical functions without using basic checklists and process flows. This leads to more than 100,000 deaths and 1.5 million patient injuries each year at an estimated overall cost of \$30 billion per annum.⁸ Such medical errors occur across all floors of the hospital and into the outpatient realm, the result of well-meaning physicians and nurses performing their jobs without adequate structure or consistency. We are at the beginning of a patient safety movement that is just starting to move into the commercial arena. Tremendous business opportunities exist in the introduction of simple, user-friendly technologies that would:

- A. Eliminate the current rate of 19 percent to 28 percent of medication administration errors which occur at the patient bedside⁹
- B. Reduce hospital-acquired infections
- C. Automate lab sample tracking and handling
- D. Provide effective monitoring and early warning systems that reduce hospital-based injuries, such as bed sores and falls

While in their infancy, patient safety product companies have begun to emerge and are demonstrating significant positive clinical outcomes, as well as strong financial return on

⁸ "Preventing Medication Errors", U.S. Department of Health and Human Services and Centers for Medicare and Medicaid Services. IOM Quality Chasm Study (2007).

⁹ "Reducing Medication Errors and Increasing Patient Safety: Case Studies in Clinical Pharmacology," J Clin Pharmacol 4.7 (2007): 768-83.

"Medication Errors Observed in 36 Health Care Facilities", Arch Intern Med. 162. 16 (2007): 1897-903.

investment for hospitals. When joined with regulation and reimbursement policies that encourage patient safety, the business opportunity here is significant.

III. Develop technology and benefit plans to deal with the diabetes epidemic

We are all familiar with the Type II diabetes epidemic and the many reasons for it. It is estimated that one in three children born today will develop Type II diabetes even though it is entirely preventable. A key challenge is that the conventional methodology of screening for diabetes is inaccurate and not administered as frequently as required. As a result, diabetes is often detected late in its development and often after irreversible damage has occurred. Moreover, diagnosed diabetics are often erratic in their efforts to manage their illness, despite the fact that Type II diabetes can be reversed or significantly controlled before it results in serious chronic side-effects. This is a problem that demands concentrated resources on many levels, as diabetes already results in an estimated \$170 billion in annual healthcare expenditures¹⁰.

Advancements in early identification and effective ongoing management of diabetes offer numerous business opportunities with the potential to deliver very meaningful cost savings as well as quality-of-life improvements. Such opportunities include:

- A. Technologies to provide low cost, highly sensitive and specific tests for early detection of diabetes and identification of at-risk (e.g., pre-diabetic) patients
- B. Consumer-focused programs to encourage prevention and wellness
- C. New health plans focused not on illness but rather on prevention and wellness, along with monitoring and stabilization of patient health. Successful administration of such plans will require unique enterprise software systems that allow for a highly patient centric experience

IV. New medical technology to enable earlier, better diagnosis and thus earlier intervention with high cost/high morbidity diseases

It is well documented that late stage cancers will typically cost 4-10 times as much to treat as cancers identified and treated at an early stage and that does not take into account the cost in human suffering that accrues when diagnoses are made at late stages of disease. As healthcare reform increases the pressure to find efficiencies, our industry must focus on those diagnostic technologies that help find disease earlier, when it is less expensive to treat. This is especially important in those situations where earlier disease identification can drive patient behavioral changes that can alter the trajectory of illness. Continued innovation around technologies which help diagnose these high cost, high prevalence diseases earlier will have a vital financial and clinical impact on our healthcare system going forward. Some of the business opportunities include:

- A. New technologies that improve sensitivity and specificity over current diagnostic imaging modalities at a lower cost. In breast cancer screening, for example,

¹⁰ Kramer, Hilary. "Diabetes is Killing our Economy". Forbes.com. 13 Jan 2010. <<http://www.forbes.com/2010/01/13/kramer-obesity-nutrition-intelligent-investing-diabetes.html>>

molecular breast imaging technology is addressing the problems of detecting early-stage lesions in the roughly 30% of women with dense breast tissue. For these women, standard mammography has poor sensitivity -- while the increasing use of MRI as a secondary screening modality results in high cost both from the test itself as well as the many unnecessary biopsies due to its relatively poor specificity.

- B. Technologies that enable *in vivo/in situ* diagnosis and real-time intervention are an emerging field that offers improved outcomes and lowered costs through earlier, less invasive and more effective treatment of disease. They can also result in avoidance of costs associated with pathology and unnecessary tests and procedures. Early examples of this approach include pill-based camera and sensor technologies, as well as probe-based confocal laser endomicroscopy (pCLE) for diagnosing disorders and early-stage cancers in the gastrointestinal tract. Soon, these minimally invasive and highly specific techniques will begin to address some of the most deadly, expensive and hard to diagnose cancers, such as lung cancer, which kills 160,000 people per year--more than the four other most common types of cancer combined¹¹--less invasive and highly specific means of finding cancer can make the difference between less expensive treatments that results in survival versus very costly treatment that results in only a few additional months of life expectancy.
- C. *In vitro* molecular diagnostic tests have the ability to detect the presence of disease, or even determine susceptibility to certain conditions, which also contributes toward earlier intervention and reduced costs. Further, molecular diagnostics will play a key role in personalized medicine which can impact costs and outcomes by directing treatments that are proven to be effective based on specific genetic characteristics – and conversely, avoid expensive therapies for patients in whom they are unlikely to work.

V. Medical devices to foster less invasive and more effective surgical interventions

We must continue to put resources behind the development of products that result in more favorable therapeutic outcome and fewer costly side effects at lower overall expense to the system. Minimally invasive technologies that reduce time in hospital operating and recovery rooms and move procedures from the hospital to outpatient settings are essential to optimizing our healthcare system.

There has already been widespread adoption of less invasive surgical products, but such products are not always coupled with reliable evidence about their clinical effectiveness. Thus, it is also important that medical device manufacturers invest in proving clinical efficacy and ensuring that systems exist to increase physician knowledge of what works best. While many in our industry fear that comparative effectiveness research will limit market opportunities for some treatment modalities, the trade-off is continued reliance on interventions that are characterized by higher cost but not improved outcomes. Innovators must embrace the movement toward comparative effectiveness and make a commitment to developing products and services that deliver meaningful clinical value for patients.

¹¹ "Lung Cancer Statistics." Center for Disease Control and Prevention. <<http://www.cdc.gov/cancer/lung/statistics/>>.

With this in mind, significant business opportunities exist in the medical device field, including:

- A. Technologies that produce more predictable and reliable minimally invasive interventions for cardiac, peripheral vascular, neurological and orthopedic conditions. Too often existing medical devices do not produce long-term positive outcomes in these areas and are highly subjective in their application.
- B. New visualization technologies that improve the surgeons ability to see deep inside the body, correct for movement and more effectively intervene surgically to produce more optimal outcomes.
- C. Medical devices and diagnostics that can be improved through convergence with information technology, telecommunications, remote monitoring, and a wide array of supportive healthcare services. Convergence technologies enable providers to take a longitudinal approach to care and allow for intervention before crises occur. Early entrants in this space have been found in implanted device monitors and remote diagnostic tools, both for cardiac applications. We believe this convergence will facilitate the more effective use of analytics and decision support tools to accelerate evidence-based medicine and the productive application of comparative effectiveness data, further contributing to the improved state of our healthcare economy.

VI. The role of healthcare information technology

The successful deployment of all of the opportunities for healthcare system improvement described above is dependent on innovation in information technology (IT). While many have come to believe, as we do, that information technology will play a critical role in advancing the cause of a more fluid and effective healthcare economy, it is a sub-sector which has been the recipient of the fewest healthcare venture capital investment dollars over the last decade. With the advent of the American Recovery and Reinvestment Act, the federal government has demonstrated its willingness to step up with billions of dollars of funding to modernize electronic medical records, recognize the critical nature that IT will play in moving the ball forward. It is now time for the venture industry to expand its sponsorship of those companies and entrepreneurs that are committed to using 21st century technologies to catalyze the innovations we need to put our healthcare economy on track for a successful future. Information technology is the bread-and-butter of the venture capital industry and thus creates a particularly fertile opportunity for those who will translate their vast IT experience into the healthcare field.

In Summary

This is an exciting time for innovators in the new healthcare economy, which should reward change agents, first movers and pioneering companies that apply methods of achieving value and efficiency. As with most mature industries, innovation is most likely to be driven by smaller companies and private enterprises, which can afford to make riskier long-term investments, while more established healthcare providers and payers focus on preserving market share and navigating reforms. Longer term, Psilos predicts those innovations will be adopted by mainstream providers and payers as the only way to achieve the dual but consistent goals of cost reduction and quality improvement.

Despite the fear, uncertainty and doubt that dominated the health reform debate, no other sector in the U.S. economy offers the combination of growth, stability and value that is presented by healthcare. The industry is one of the largest segments of the U.S. economy, with total spending expected to nearly double to \$4 trillion by 2015, according to the National Coalition on Healthcare. In 2008, while the overall U.S. economy lost more than 2 million jobs, the healthcare sector added 500,000 – the only sector to experience significant growth, according to the Bureau of Labor Statistics. Healthcare spending has historically been immune to periods of market downturn, and will only grow faster with the addition of 32 million newly insured Americans and the doubling of our elderly population by 2050. Notably, venture-backed companies are the largest source of these new jobs, contributing eight times the job growth in 2006-2008 as compared to private sector job growth as a whole, according to NVCA.

It is clear that the American healthcare economy is a market poised for transformation. The passage of such landmark healthcare legislation, imperfect as it may be, creates significant impetus to develop and market sound ideas and technologies that will improve the health of our healthcare system. As the federal budget deficit and economic pressures place even greater focus on the need to address the rising cost of healthcare in America, the market is especially ripe for new business models and innovative solutions to reduce the cost of delivering healthcare across our citizenry while improving the quality of care available across the board. Failure to invest in innovations to cure our healthcare system's ills will lead us down a treacherous economic path that affects all of our markets and the very competitiveness of American industry. Now, more than ever, there is a rising demand for new business solutions that deliver real value for each healthcare dollar spent by the federal and state governments, U.S. corporations and individual healthcare consumers. This creates tremendous business opportunity for those who sponsor the development of products and services to address the demand for innovation that such a wholesale change in the healthcare marketplace portends. With the onset of a serious attempt at healthcare reform, the venture capital industry has a unique opportunity to rise to the occasion and spur the next industrial revolution—one that enables investors to do well by doing good—in establishing a high-function, high-quality healthcare economy.

About Psilos Group

Psilos Group Managers, LLC ("Psilos") is a venture capital firm focused on providing venture and growth capital to companies operating in the healthcare economy. The firm believes that successful healthcare innovation must reduce cost, improve quality and align incentives across payers, providers and patients. Founded in 1998, Psilos has \$580 million under management and invests across three core healthcare sectors: healthcare services, healthcare information technology and medical technology. Funds managed by Psilos have invested in such marquee companies as ActiveHealth, AngioScore, Click4Care, Definity Health, Extend Health, SeeChange Health, QualityMetric and OmniGuide, among many others, which have played, and continue to play, key roles in the transformation of the U.S. healthcare economy. Psilos has offices in New York, the San Francisco Bay Area and Santa Fe, New Mexico.



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