Innovating for More Affordable Health Care

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Exploring new ways for social investors to spur innovations that create better, faster, and less expensive health care in the United States.

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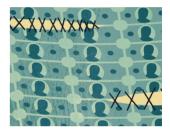
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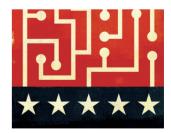
Social investors are experimenting with a profusion of creative funding mechanisms to help innovators sustain health-improving approaches and to achieve greater impact.

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Framing the Issue

Innovations for better care at lower cost.

BY MARK SMITH AND BARBARA LUBASH

ealth care in America has increasingly priced itself out of the reach of customers. Consumers and employers have long complained about the system's lack of affordability. And the payer of last resort—government—is now facing the same reality.

Indeed, the current debate over how to manage the country's deficit has produced a striking milestone in American politics: Bipartisan agreement essentially exists on the need to dramatically rein in government health spending. The argument is not about whether to cut costs, but how.

Some see innovation as the principal problem in health care, concluding that the hunger for the latest new technologies and devices, without regard to value, has brought the nation to this point. Although there is no question that high-cost, low-value products

and services have been created in the name of innovation, we believe that bold new clinical and business models, often aided by technical breakthroughs, are instead a vital part of the answer.

At the <u>California HealthCare Foundation</u> (CHCF), we have collaborated with academics, philanthropists, investors, and entrepreneurs to support innovations that provide better care at a lower cost. And we have had some successes—such as a low-cost, technology-enabled program that screened more than 53,000 diabetics who otherwise wouldn't have access to eye specialists, and saved the sight of more than 1,400 Californians.

But too often we have seen the paradox of a "successful" pilot that has failed to gain wider traction. Numerous challenges face innovators during the early development of new care models, perhaps the greatest of which is bridging the gap from testing and early adoption to mass adoption. Crossing this chasm requires extraordinary leadership, entrepreneurship, and collaboration among creative talent of all kinds.

Our experiences in the field have led us to create the <u>CHCF</u> <u>Health Innovation Fund</u>. The initial \$10 million fund is dedicated to identifying and investing in both nonprofit and for-profit companies developing technologies and services that have the potential to create a dramatic impact on the cost and accessibility

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of care. As we developed the fund, we paid close attention to the creative approaches of other health care foundations in this area. Although most "impact investing" in health care to date has been from foundations working internationally, we see a growing interest among social investors and entrepreneurs in tackling health care

costs and inequities *inside* the United States.

This sponsored supplement to the *Stanford Social Innovation Review* explores the challenges of investing for lower-cost devices, services, and technologies in health care. The topic is ripe for inquiry, given the pace of innovation in health care and the significant funds that flow from traditional investors into the sector each year.

The report begins with an article by Stefanos Zenios and Lyn Denand at the Stanford Graduate School of Business that explores the challenge of funding innovations for the health care "safety net," or those providers

who care for low-income populations. To follow this piece, we invited two investors and an entrepreneur to offer their perspectives on the challenges and opportunities in health care innovation.

In addition to new technologies, new models for service and care delivery also will have to be invented if the United States is to meet a growing need for health care within a shrinking budget. Arnold Milstein, MD, explains what he is hoping to achieve in this area through the work of the Stanford Clinical Excellence Research Center.

Because the government pays for nearly 50 percent of the nation's health care costs, we have included a piece from Carleen Hawn about how Todd Park of the US Department of Health and Human Services is trying to infuse the innovation culture of Silicon Valley into the largest of bureaucracies. And for a perspective on cost-lowering innovation in the developing world, we have Jaspal S. Sandhu's examination of how global initiatives in mobile health might inform care in the United States.

In the final article, John Goldstein, co-founder of Imprint Capital Advisors, and Margaret Laws, director of the Innovations for the Underserved program and the CHCF Health Innovation Fund, describe some of the ways that foundations are using their capital to support emerging market-based approaches to health care innovation.

We hope that this collection captures the creativity and excitement we see coming from innovators, investors, and providers who are joining together to take on the formidable challenge of innovating for high-quality, lower-cost care. \blacklozenge

Investing for the Safety Net

Technologies that reduce costs and improve care for the underserved are often the most difficult to scale up. But a handful of strategies could turn things around.

BY STEFANOS ZENIOS & LYN DENEND

n 2010, <u>BeWell Mobile</u> faced a dilemma all too common among startups in the health care field: how to fund the growth of breakthrough innovations that both lower costs and improve the standard of care when the patients and providers who often benefit the most have the least ability to pay.

The San Francisco company develops customized disease management software that operates on devices like cell phones. In an eight-month pilot study with the San Mateo Medical Center, funded by the California HealthCare Foundation, 50 bilingual, uninsured teens with severe asthma recorded their symptoms by phone at least once a day using BeWell's technology. The real-time feedback, reminders, and other interventions they received in response caused the patients' drug compliance to more than double, their need for rescue medications to be cut in half, and their visits to the emergency room and their days of missed school to fall dramatically.¹

In most fields, results like these would have had investors beating down the doors. But despite the promise of its technology, BeWell hasn't been able to demonstrate a business model that resonates with venture capitalists. In the current health care system, clinicians aren't reimbursed when poor patients on Medicaid avoid going to the hospital—only when they receive care. In effect, Medicaid accrued the benefits of keeping the pilot program's patients healthier and reducing the overall cost of their care, while the physicians at San Mateo Medical Center who did the work received little financial reward. In this scenario, it's no wonder that the hospital decided it couldn't justify a longer-term investment in BeWell's technology.

BeWell's story illustrates the challenges facing companies that try to enter underserved markets, defined as low-income people and the health care providers who serve them. In particular, this segment of the health care field has a significant need for new medical technologies that expand access to important diagnostics, treatments, and specialty services while reducing costs—all without sacrificing the quality of care. Think of remote monitoring technologies that check on the vital signs of the elderly, people with chronic health conditions, or those recovering from a serious illness so as to enable providers to intervene before a crisis occurs.

Many of these technologies have the potential to help underserved populations that receive care from so-called safety net providers. Such providers serve disproportionate numbers of the uninsured and those on Medicaid by offering free or discounted care. They include public hospitals, community health centers and clinics, and for-profit and nonprofit health care organizations.² Because of their mission and the socioeconomic status of the majority of patients they serve, safety net providers face severe resource constraints.

The problem is that traditional funders of health care innovations, such as venture

capitalists and corporate investors, are seeking significant rewards to compensate for any risk they take. "Investors are looking for unbounded upside with the least amount of risk possible," said Josh Makower, founder and CEO of device incubator ExploraMed. But, he explains, "Most investors don't expect to find big, unbounded opportunities in low-resource environments."

Medical technologies with high social value—those with the potential to reduce costs, improve outcomes, and increase access for underserved populations—can play an important role in helping safety net providers use their resources more efficiently to better serve millions of patients. But these products and services may not necessarily generate the high financial returns that investors expect, particularly when the benefits are misaligned, as in the BeWell example. For this reason, many companies have struggled to secure capital to fund the development and commercialization of important innovations.

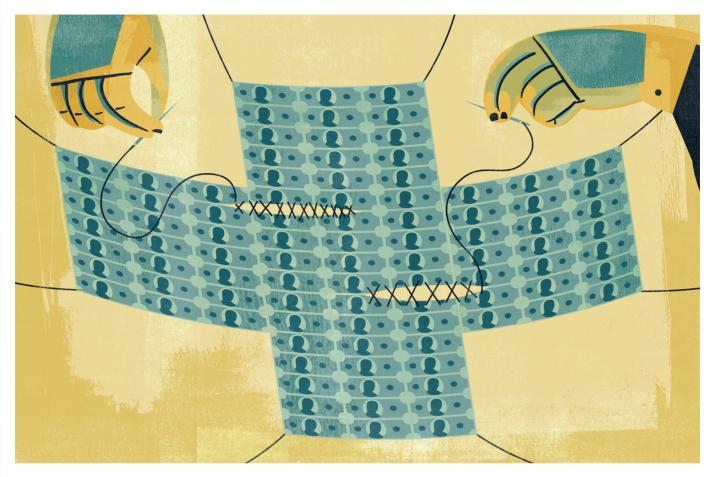
This misalignment between the risks and rewards associated with innovative new technologies must be overcome if the United States is to improve its health care system significantly over the coming decade.

HOW TECHNOLOGIES GET FUNDED

Medtech innovators typically have two choices when seeking the cash they need to achieve scale: venture capital and corporate investment. Venture capital is by far the largest source of funding in the medtech field. In 2010, for instance, US venture capitalists invested \$2.3 billion in 324 medical device startups, according to PricewaterhouseCoopers.

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Venture capital, also referred to as venture financing, typically helps startups establish or sustain a business with high growth potential. A venture capitalist (VC) makes an investment, and in exchange, the VC's firm receives equity in the company. The expectation is that the investors will be able to realize a substantial return on their money through an "exit event," such as selling the company to another firm, at some point in the future. This type of funding is especially helpful to startup companies that do not yet have an operating history, revenue, or significant collateral, and therefore lack access to other sources of capital, such as bank loans.

In the medical devices sector, VCs select their investment opportunities using specific criteria that help them balance the risk-reward equation. Although every VC takes a slightly different approach to evaluating new technologies, there are some common criteria that they all use, such as the strength of the management team, the technical feasibility of the product, and the size of the potential market. (See "What Venture Capitalists Look for in Medtech Investments" on page 6.)

In combination, these criteria assist VCs

in placing their bets. The more risk they see as they evaluate the opportunity, the greater the market size and potential return on investment must be to get them interested. Because a large portion of venture capital deals fail to earn any return on investment, those that succeed must compensate for the losses. "If roughly 20 percent to 40 percent of companies succeed, you need these companies to make up for the capital invested across the portfolio and generate a return for investors," says Mudit Jain, a partner with venture capital firm Synergy Life Science Partners. Returns for VC-funded companies considered to have achieved a successful exit range from 300 percent to 1,000 percent, or three times to 10 times the total investment.

Another common funding source for medtech innovators is corporate investment. Large corporations, such as Johnson & Johnson and Medtronic, can help fund startups by underwriting a specific research and development effort through a development partnership or by investing in the company as a traditional VC would. Corporations have criteria similar to those that VCs use when evaluating opportunities. Unlike venture investors, however, corporate investors are

looking for investments that will also create synergies with other products in their portfolios or new opportunities aligned with their growth strategy. If a new technology is strategically attractive, a company may be slightly more flexible than VCs when making an investment.

THE TWO SIDES OF THE SAFETY NET MARKET

Unfortunately for innovators who want to develop technologies that aid underserved populations, VCs and corporate investors use the same demanding criteria to evaluate these technologies as they use to assess mainstream commercial opportunities. What's more, VCs today face even greater pressure to produce results, and they may have less money to invest than in the past. In combination, these factors can make it difficult to get funding for technologies that could benefit the safety net but pose greater investment risk.

"The investors we represent don't look to us to do their humanitarian work," says Michael Goldberg, a partner with venture capital firm Mohr Davidow Ventures. "They look to our firm to generate a return on

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their investments in a way that's hopefully compatible with their humanitarian values. If we told them we were going to sacrifice investment returns in any material way in an effort to better serve the general welfare of the US or world population, I think they would move their money as soon as they had the opportunity."

When asked what advice he would give to innovators seeking funding to meet clinical needs in low-resource settings, William Starling, managing director of Synergy Life Science Partners, says bluntly: "Avoid venture capitalists. Venture capitalists are trving to survive. There's just no way they're going to put money into efforts that don't meet the minimum bar for return on investment in the current climate."

Despite the perception that low-resource environments can't generate big returns, the safety net shows some promise as a market opportunity for commercial investorsspecifically, it can be used as a launchpad for cost-reducing technologies. As the entire health care system becomes more cost constrained, technologies that can reduce spending should become more broadly appealing. Proving the value associated with these products under the challenging conditions of the safety net could potentially help them cross over into mainstream commercial settings. In the process, it would help establish the safety net as a preliminary market from which companies could expand.

Innovators can also consider expanding from the safety net into low-resource environments abroad. "If you can actually find a solution that makes sense in [US-based] resource-constrained environments, you may be able to enter the true growth markets of tomorrow," says Ed Manicka, CEO of medical device maker Corventis. "Specifically, India and China are demanding low-cost solutions that are technologically on par with what is available in the United States. Now, clearly, the margins are going to be lower, but the pure scale is mind-boggling."

Finally, the size of the underserved population, although small compared with the total US market, is still substantial. Medicaid covers roughly 48 million low-income families and another 14 million elderly and people with disabilities. Total Medicaid spending for fiscal 2010 was approximately \$365 billion, almost a 9 percent increase over the previous year, and the budget is expected to continue growing for the foresee-

What Venture Capitalists Look for in Medtech Investments

CRITERIA	VCS LOOK FOR
Business model	A clear, practical plan for making money
Technical feasibility	Technology that has been proven to work, at least in bench or animal tests
Management team	Experienced leadership with a proven ability to execute
Market	Technology that corresponds to a significant validated clinical need
	Target customers who are enthusiastic about the solution and relatively easily accessible through traditional sales channels
	Limited competition
	Total market opportunity greater than \$400 million
Return on investment	Returns of three to five times the investment (10-times returns are the benchmark)
	Exit within three to seven years (the longer the exit horizon, the greater the expected return)
Intellectual property	Clear, uncontested patent protection
Regulatory	A straightforward regulatory pathway, preferably via a 510(k) in the United States rather than the FDA's more expensive, time-consuming, and risky pre-market approval process
Reimbursement	Established Medicare reimbursement codes and high payer receptivity to covering the technology

able future. Although there are significant challenges associated with reaching and serving these patients and their providers, the population represents a sizable opportunity for innovators who can figure out how to serve it profitably with high-value, lower-cost solutions.

THE CASE OF REMOTE MONITORING

A specific class of products known as remote-monitoring and intervention technologies illustrates the challenges and opportunities that innovators face when they seek venture funding for innovations that have high social value. Although remote monitoring can potentially reduce costs, improve care, and increase underserved patients' access to specialty care, venture investment in this area has been slow and somewhat inconsistent.

Devices like blood pressure cuffs and glucose monitors enable physicians and other care providers to check and treat patients' conditions without being physically present. Costs can be lowered when care shifts to a less expensive setting, such as a clinic or a patient's home. By keeping people out of the hospital, these solutions can also significantly help improve people's quality of life.

When VCs and corporate investors evaluate remote-monitoring technologies using their standard investment criteria, many innovations receive high marks for technical feasibility. "Remote-monitoring technologies are relatively low-tech in some ways-I mean, it's not like we're putting devices inside the body that are going to shock a patient's heart," says Suneel Ratan, a marketing, reimbursement, and government relations executive at Robert Bosch Healthcare, a leading corporation in the telehealth field. Most of these products are based on fundamental technologies that have proved themselves in sensors, data communications, or other fields.

Moreover, because the devices are for external use, they pose few safety risks for patients. As a result, they often receive regulatory clearance through the FDA's faster 510(k) review process. Most investors favor 510(k) products over those that require pre-market approval, and thus they may be more attracted to remote-monitoring innovations.

Although the technical and regulatory risks are relatively low, several other investment criteria have proved to be problematic for many remote-monitoring solutions. Investors frequently decide not to fund the technologies because of a combination of market and adoption risks, as well as issues regarding business models and reimbursement. Investors are also hesitant to commit resources because they perceive a low potential return on investment. Each is a significant barrier that must be overcome in order for new technologies to move forward. (See "Remote-Monitoring Risk Factors" below.)

The story of Health Hero Network illustrates each of these barriers to funding, as well as the challenges traditional investment criteria create. At the time Health Hero Network was established in 1998, the Palo Alto, Calif.-based company's primary product was the Health Buddy System for monitoring and improving the health of high-risk, high-cost elderly and disabled patients with one or more chronic conditions.

Patients used a simple, four-button device that each day led them through interactive sessions of six to 10 questions customized for the person's condition. Primary care physicians and specialists prescribed Health Buddy to teach patients how to understand their conditions better. help them change their behavior, enable the early detection of health risks before they escalated to an acute stage, and provide reassurance to patients that their health was being monitored. Health Hero Network supplied the technology and training for users; the health care provider set up the basic infrastructure for receiving, interpreting, and acting upon data transmitted from patients' homes.

After Health Hero Network developed the technology, it conducted a series of demonstration studies to prove the system's value. A small early study with the health plan PacifiCare showed a 50 percent reduction in hospital readmissions for heart failure patients who used Health Buddy, according to Ratan. Despite these encouraging results, PacifiCare eventually decided to outsource its disease management services rather than adopt the technology.

In 2000, Health Hero Network launched a pilot with the Veterans Administration (VA) in Florida. The study of 900 patients using Health Buddy found a 63 percent reduction in hospital readmissions and an 88 percent decline in nursing home days.³ Approximately four years later, Health Hero received its first national contract with the VA. The agency agreed to directly fund the purchase and use of Health Buddy technology and related services.

Health Hero Network then approached the Centers for Medicare & Medicaid Services (CMS) about securing reimbursement for its product. "The largest and most expensive group of patients you can go after globally is the folks on Medicare," Ratan says. "[Health Hero Network] had a desire to prove that health care management interventions with the Health Buddy would generate a similar result in a fee-for-service system." The company submitted a proposal to CMS and got approval to launch a three-year demonstration study in 2006. The results have not been officially released, although Ratan described them as "jawdropping." CMS extended the demonstration project in 2009, but as of this writing has not yet decided whether to grant reimbursement for the product.

Robert Bosch Healthcare acquired Health Hero Network in late 2007, when more than 20,000 people with chronic conditions were using Health Buddy. After receiving about \$72 million in total known funding, the company was sold for \$116 million, a return of roughly 1.6 times the investment.

In deciding to sell the company, Health Hero's board presumably determined that an exit at that point was financially more attractive for its investors than the alternative of raising more capital in order to drive reimbursement changes and increase market adoption. The funding environment in 2007, along with the company's progress to date, most likely made it difficult for Health Hero's investors to envision a compelling return on investment from putting in more money and extending the investment time horizon.

Other risk factors also played a role in preventing Health Hero from raising additional capital to commercialize the Health Buddy product on its own. The high burden of proof required to change physician behavior and drive widespread market adoption turned out to be time-consuming and costly to the company, causing it to burn through the funds it had already raised. Adoption was also limited primarily to integrated health care providers like the VA, which could benefit from the longer-term, system-level savings associated with such improvements as reduced hospital admissions. Fee-for-service providers remained unconvinced of its value, especially without reimbursement for activities or technologies that keep people out of the hospital. That reduced the size of the market in the near term. As Ratan explains: "The premise of the Health Buddy system is chronic care. It's continuous, supportive, and designed to build an individual's capability to take better care of himself. But the health care system is engineered for acute care-the incentives are structured largely to wait until someone's in crisis."

STRATEGIES TO ADVANCE THE FIELD

New technologies, such as the Health Buddy and dozens of others like it, have the potential to reduce costs, improve health outcomes, and increase access to the services patients most need. But the social benefits these innovations create are undervalued in the way traditional VC and corporate investors make funding decisions. Foundations, social venture funds, individual philanthropists, and other socially minded investors can play

Remote-Monitoring Risk Factors

CHALLENGE	RISK
Market/adoption	Physicians often resist technologies that disrupt the tradi- tional approach to care.
	Fixed investment in facilities, staff, and equipment may ampli- fy that resistance if the technology shifts care to other venues.
	A high burden of clinical proof is necessary to establish a new standard of care.
	Providers may not want to build and manage the service infra- structure necessary to support the technology.
	No incentives exist to help offset the additional liability phy- sicians may face by using remote monitoring.
Business model/ reimbursement	Few proven business models can serve as precedents. The current reimbursement system creates disincentives for providers to adopt innovative approaches.
Return on investment	The size of the target market may not align with the capital necessary to overcome the risks.
	Risks may extend the time to exit.
	Exit options are limited.

an important role in correcting this market failure by altering investor perceptions of the risk-reward equation associated with these technologies. They can do this in three primary ways.

Fund Meaningful Pilot Studies to Reduce Safety Net-Specific Risks After identifying the most promising technologies with high social value, social investors can help them succeed by underwriting and facilitating compelling pilot studies and clinical trials. This would directly reduce one of the most daunting costs of bringing promising innovations to market and could significantly reduce the time it takes to develop the clinical proof needed to catalyze provider adoption.

Such studies can also be designed to improve the attractiveness of the safety net as a market. There's a common perception that safety net patients are less likely than other populations to comply with their prescribed treatments-including the use of technology. Rigorous studies with results that stand up to peer review may be able to demonstrate that underserved populations are no less compliant than other market segments. If particular patient groups continue to show difficulties with compliance, social investors might support the piloting of innovations to minimize these issues-for example, by shifting the burden of treatment or testing from the patient to the provider or by making patient requirements more fail-safe.

To get good value from the studies they fund, social investors must think more strategically than they have in the past about what to test, how to test it, and what data should be generated. The majority of pilot studies should include controls, produce publishable results, and include a rigorous economic evaluation of the technology, so that decision makers who can influence adoption perceive the data as credible.

To accomplish these objectives, social investors can collaborate directly with payers to determine the kind of value proposition data—cost savings, improved care metrics, and so on—they would want to see before they would be willing to pay. Then they could design and fund a pilot to gather those data. In the BeWell example at the beginning of this article, the company might have generated greater interest from investors and health care providers if its pilot study had been specifically designed with the goal of demonstrating significant value for customers and determining the return on investment required for adoption. That, in turn, might have eliminated some of the risks for traditional venture investors and health care organizations. Translational work of this kind would help innovations get uptake in the market and attract investment.

Change Policy In parallel, social investors can help address business model and reimbursement-related risks, such as the ones Health Hero Network faced, by urging CMS and federal lawmakers to realign incentives in the current reimbursement system to support the use of technologies that reduce costs, improve care, and increase access, even if this means shifting the venue or disrupting the traditional model of care.

Existing incentives for "closed" health care providers, such as the VA, Kaiser Permanente, and other managed care organizations receiving fixed payments for services, may be adequate as long as sizable, long-term capital investments are not necessary. But direct reimbursement for innovative new technologies would certainly strengthen their motivation. It would also make the technologies more appealing to providers that still serve fee-for-service Medicaid and Medicare patients.

In 2011, a unique opportunity exists for social investors to interact with the new Center for Medicare and Medicaid Innovation, which Congress created under the Affordable Care Act. This division of CMS has a mandate to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for Medicare and Medicaid recipients. It has been given \$10 billion in funding to explore new payment models between 2011 and 2019, which means that social investors are perhaps better positioned than ever before to collaborate with the center and influence its policy recommendations.

Another aspect of the Affordable Care Act that may present opportunities for social investors to effect change is the introduction of accountable care organizations (ACOs). ACOs are virtual networks of doctors and hospitals that share responsibility for providing care to a defined population of patients over a specific period of time. The ACO concept is intended to make groups of previously disconnected providers jointly accountable for the health of their patients, giving them stronger incentives to cooperate and save money—for example, by avoiding unnecessary tests and procedures. With these new incentives, technologies that keep patients out of the hospital may become appealing to traditional fee-forservice providers that previously wouldn't have considered them.

The details of the ACO model still remain to be proven, but social investors can lend valuable insights as policymakers and providers figure out how to make the approach work. For instance, investors who are considering ACOs as potential buyers of medical technologies may be concerned that they will face long sales cycles that require approvals by the network's board of directors before new products can be adopted. Social investors can potentially anticipate such risks and, through the pilot studies they support, gather data aimed at shortening sales cycles for ACOs.

Establish Dual-Market Potential Because subsidized business models are rarely sustainable over the long run, social investors have a vested interest in increasing the crossover potential of cost-saving technologies that have been shown to serve safety net populations effectively. Reimbursement reform and the advent of ACOs will potentially increase the opportunity for technologies optimized for the safety net to penetrate commercial markets in the United States. Specifically, reimbursement reform will create incentives to encourage the adoption of new technologies among Medicare fee-for-service providers *beyond* the safety net (with private payers following Medicare's lead in granting reimbursement). Similarly, ACOs will involve not just Medicare and Medicaid beneficiaries, but patients with private insurance as well, thereby giving private payers another reason to think differently about preventive care. By supporting these policy changes, social investors will help establish dual US markets for safety net innovations.

Social investors can further support technology crossovers by coordinating networks of VCs with an interest in investing in overseas markets and introducing them to technologies that reduce costs while improving health outcomes. Outside the United States, large emerging markets in countries like India and China are attracting significant attention. Some of the technologies that have been shown to deliver value to safety net providers may be strong candidates for improving health care in the developing world for tens or hundreds of millions of customers.

FUNDING SOCIAL INNOVATIONS

When it comes to funding innovations with high social value, social investors can use several models. Targeted grantmaking is perhaps the most common form of support that foundations, philanthropists, and government agencies offer. Innovators receive financial support from these entities with no expectation that they will repay the money. With effective targeted grantmaking programs, such as the US Small Business Innovation Research (SBIR) program, funding is awarded for a specific purpose (for example, conducting a defined pilot study) and must be linked to a specific commercialization plan for moving the technology to market.

Program-related investment is another common form of funding. It has been around since 1969, but it has become increasingly popular over the last 10 years. Recognizing some of the inherent limitations of grantmaking, such as the dependence these subsidies can create, social investors like the Acumen Fund developed processes for providing "social capital" to bridge the gap between the efficiency and scale of commercial venture capital and the social impact of pure philanthropy.⁴ With these models, capital is raised from donors (typically large foundations) and then invested in fledgling companies with products and services that have the potential to generate high social impact, achieve scale rapidly, and become self-sustaining within five to seven years.

The companies benefiting from program-related investments might be given loans, guarantees that allow them to access capital through other channels, or investments in exchange for equity. The social investor expects to earn a return on its money, but the rates, investment horizon, and other terms are less stringent than traditional venture requirements. Acumen Fund, for example, expects that approximately half of its investments will succeed and half will fail. For this reason, it hopes to realize a twotimes return on its successful investments, so that 100 percent of all capital raised from Acumen donors can be reinvested multiple times.⁵ Other entities recycling donor capital in this way within the health care field include the Bill & Melinda Gates Foundation.

the Robert Wood Johnson Foundation, and the California HealthCare Foundation with its Innovations for the Underserved fund. (For more information about this strategy, see "Foundations as Investors" on page 21.)

Social venture funds are yet another source of capital. With this type of financing, no donors are involved; foundations, corporations, and high-net-worth individuals make debt or equity investments into a fund and become limited partners, as they would with any private equity or venture fund. The fund pursues a social mission, however, in addition to seeking to generate a financial return for its investors. "Investors take an outsized risk for the ability to have a social impact," explains Raj Kundra, director of capital markets at Acumen Fund. The Acumen Capital Market fund has attracted investments from such high-profile foundations as Rockefeller and Skoll. By offering returns, even though they might be below market rates, fund managers are able to raise and deploy significantly larger amounts of capital than they could by raising donations for grants or program-related investments.

Foundations, in turn, contribute to these funds to help technologies with high social value reach a point at which they are attractive to traditional investors. As Kundra says, the goal of impact investing is to provide a proof of concept for interesting technologies and then bring in new sources of capital once these innovations are far enough along to meet more traditional investment criteria.

A fourth funding option focuses on commercializing innovations developed in academic settings. From 2006 to 2011 the Wallace H. Coulter Foundation awarded grants of \$5 million to nine universities. The schools used the money to provide seed funding to projects that had the potential to generate treatments and devices that improve human health. At Stanford University, one of the grant recipients, 25 such projects were funded during the five-year period. A panel of academics, entrepreneurs, and investors selected the projects, and each one followed a rigorous development process that included a detailed commercialization analysis. Almost half of these projects moved toward the marketplace as a result of the funding, and they have secured \$43 million in follow-on funding, with 49 percent from nongovernment sources.

Following on the success of the program, the Coulter Foundation established a \$20

million endowment at Stanford to support funding of such translational projects in perpetuity. By staging its investment, the foundation proved that a rigorous development process can work in an academic setting to increase the rate at which new technologies reach the market. It also demonstrated how such an approach can accelerate the translation of early-stage discoveries into marketable products. Other foundations with an interest in supporting the development and commercialization of products or services that can reduce the cost of health care in environments with limited resources—without sacrificing quality-could potentially pursue similar funding models.

CONCLUSION

Nearly all health care stakeholders now believe that the future of the entire system depends on gaining better control of rising costs. As a result, interest is growing in innovations that enable more efficient and cost-effective care. Traditional investors appear more open to funding such projects, as long as they can generate sufficient financial returns.

Social investors can play an important role in this movement. They can identify opportunities to reduce risks, change policy, and help establish dual markets for bold, potentially market-transforming ideas that otherwise could struggle to raise funding from traditional sources. They can also provide flexible, long-term capital in the form of targeted grants, program-related investments, social venture funds, or endowments. Through these mechanisms, donors, investors, funders, providers, and innovators can help ensure that high-impact innovations find their way to the patients who need them the most. \blacklozenge

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PERSPECTIVES FROM THE FIELD

Two investors and an entrepreneur take on the challenges facing innovators.

Innovation Is Only Half the Answer

BY LISA SUENNEN

ith health care costs at an all-time high and quality of care under siege, more of the same isn't going to cut it. The United States needs innovation, not incremental change, to cure its ailing health care system. Fortunately, public and private organizations have made it their mission to catalyze innovations that solve the thorny challenge of providing better health care services to more people with less money. Nearly every major US health care corporation and foundation seems to have a newly minted center for innovation. The nonprofit <u>X PRIZE Foundation</u> will award \$10 million to those who "accelerate the real-world impact of science, technology, and information." <u>The Center for Medicare and Medicaid Innovation</u>, the <u>Agency for Healthcare Research and Quality</u>, and the <u>Office</u> <u>of the National Coordinator for Health Information Technology</u> have all launched high-profile innovation initiatives.

Although this quest is laudable, the arrow may well fall short of the bull's-eye. Most of the innovation efforts are designed to reward the creation of great ideas but not to deliver real systemic change. That's because they fail to take into account a last critical step: turning ideas into reality.

Too often, these programs disregard how innovations will be funded, commercialized, adopted, and spread into common use. The public sector in particular has demonstrated a worrisome reluctance to analyze leadership and operational capabilities as an intrinsic part of determining the quality of an innovation. Few require the winning ideas to be married with driven, strategicthinking entrepreneurs who know how to turn lightbulb moments into broad-based reality.

The guiding principle of many innovation competitions has been "if you build it, they will come." Those who build businesses for a living know this is almost never the case. Social investors gloss over these issues at their peril.

The pursuit of "innovation" just isn't specific enough. The field needs a combination of innovation and entrepreneurship to move the needle.

Experience shows that an idea is only as good as the leader who figures out how to implement it. Too often innovators, focused on the needs of the underserved, shy away from traditional business ideas like marketing plans and capital formation. Because many solutions for the underserved will emanate from public-private partnerships, public innovation seekers must apply the same rigor that venture capitalists require when they vet new ideas. Any analysis of the quality of an innovation must be balanced with an analysis of the leadership behind it, the plans for scaling it, its ability to demonstrate measurable results, and its financial viability. Although these analytical criteria are often considered the purview of the business community rather than the public health sector, they are essential to transforming innovations into solutions.

In addition to prizes and public accolades, health care innovation initiatives would fare better if they actively partnered thoughtful innovators with entrepreneurs seeking to launch commercial enterprises and if they helped them attract the capital to bring ideas to market. Innovation itself is abundant, but innovation guided by a great leader with a strategic implementation plan is not.

A good idea with a great leader beats a great idea with a good leader any day of the week. When great ideas and great leadership come together, real innovation can happen. \blacklozenge

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Collaboratively Investing for the Future

BY WILLIAM ROSENZWEIG

enture capitalists generally look for opportunities that can achieve rapid consumer adoption once they prove their worth to a test market. We look for early adopters who enthusiastically share a product with others and sometimes even pay a premium for it. Regretfully, underserved populations rarely have the means or access to be early adopters in these conventional terms.

Several years ago we funded a company with an innovative product that could prevent serious asthma attacks. The company's nutrition bar was particularly well suited to the unmet needs of atrisk children in polluted urban centers. The product had the potential to bring down the use of steroid drugs and costly inhalers. Most important, this nutritional product could reduce the number of costly emergency room visits that plague inner-city hospitals on the bad-air days that make asthma worse.

Although this market was vital from a public health perspective, it lacked the commercial characteristics that would have made it attractive to early-stage venture investors. The company instead chose to pursue an adult market in which it had to compete with established pharmaceutical companies, which proved difficult.

Had this company partnered with an impact investor who had

expertise with underserved populations, it could have built a credible business case to pursue a niche market in the inner city. (Such an investor wasn't available at the time, unfortunately.) An innovative financing and partnership structure could have made use of the existing research and product development investments in a capital-efficient way that demonstrated broad application for the product. The company could also have enlisted a corporate partner with the deep expertise needed for commercial success.

But such innovative arrangements are far from easy when organizations with different definitions of success and vastly different cultures try to collaborate.

It doesn't have to be that way, however. Odd-bedfellows partnerships can actually succeed when the partners have a shared sense of vision, mission, and values.

Successful partners need to be clear about what success looks like to all the parties—including expectations around markets, business models, returns on investment, time frames, capital requirements, scale, and exit options. These expectations must be shared, specified, and agreed upon at the outset. If this initial process yields promising results, innovative limited partnership models can assign different parts of the risks and the rewards to appropriate stakeholders, who can build a venture with the potential for strong financial rewards and meaningful impact. Organizations then can create a governance structure that helps them navigate the stages of growth, stay on mission, and achieve the kind of performance that will satisfy expectations.

Partners collaboratively build a bridge from where an organization is today to a clearly defined vision for the future. Organizations *plan* to be successful. From the beginning, they gather and align all the resources they need to get to the desired outcome.

Unfortunately, many ventures are built phase to phase, without a coherent set of partners around the table at the outset. Because of this, many efforts go uncompleted or are unable to maintain the momentum or attract additional resources along the way.

Regardless of outward appearances, organizations would be wise to look for unlikely partners with whom they are aligned on vision and with whom they can plan for the long term. The United States faces daunting health care problems. Despite the challenges, the field can collaborate with potential investors who have the financial and social missions that can make a difference. \blacklozenge

WILLIAM ROSENZWEIG is a managing director of Physic Ventures, a venture capital fund that invests in keeping people healthy.

Lessons from an Innovator

BY CHAIM INDIG

ow is a great time to be in health care. The industry is changing and innovation is improving people's lives. In 2005, we started <u>Phreesia</u>, which automates patient intake at doctors' offices. Our product replaces the traditional paper clipboard with a wireless, touch screen tablet, allowing patients to enter their demographic, insurance, and clinical information electronically, as well as to pay their co-payments and balances. Phreesia streamlines the check-in process for office staff and patients and facilitates better patient-doctor communication. It provides a foundation for lower-cost, higher-quality care as well.

Our technology is now in thousands of physician offices across the country. We are also providing a platform for a range of health improvements, from more effective management of asthma to early detection of autism to expedited treatment for acute care patients.

I have learned some important lessons in developing Phreesia, bringing the company to market, and overcoming a number of barriers to adoption. First, the biggest challenge to innovation in health care is fear of change. Providers and administrators are afraid of the repercussions that new technology will cause to their institutions and day-to-day workflows. These systems often require changes to behavior, staffing, and expectations that can be overwhelming.

Moreover, the bureaucracy at many health care institutions makes large-scale change difficult to implement. In the early stages of the business, one of the biggest hurdles we faced was finding customers who were open to modifying the ways they worked even when they understood the benefits of engaging patients, maximizing efficiency, and increasing collections.

To get around these roadblocks, we made our product as high impact as possible, with minimal up-front costs for customers, and we built our business model around performance. Phreesia does not interrupt the normal ways that physician offices work, which helps ease the transition for staff. We are not trying to change an office's workflow; we are simply adding value and efficiency to their existing processes, and fitting in with the existing reimbursement model.

Another major obstacle to innovation has to do with the way the industry reimburses providers. In other industries, companies develop their product or service knowing exactly who will buy it. But in health care, the reimbursement model is much less straightforward: The people who use the new technology are different from those who benefit from it, and they are also different from those who pay for it. Because of this disconnect, health care innovators need to demonstrate value for each of their stakeholders, and they need to make their case in a compelling way.

Further adding to the challenge, the current reimbursement model does not directly benefit those who need innovation the most, so there is often little motivation for safety net organizations or health care systems to take on changes that could improve health and lower cost.

And finally, the most important lesson: Success in health care does not come from the idea, but from executing that idea within a sustainable business model. When we first started Phreesia, we did not raise any outside funds. In our opinion, the most important thing was not to raise money, but rather to assess the market and find a replicable solution to a common problem. Once we found customers who wanted our product, we began to commercialize it. We have always looked for, and have been lucky to find, partners who not only invested in our business, but also offered strategic guidance to help us grow and achieve ongoing levels of excellence.

Ultimately, our story shows that with a smart and motivated team of people who are always searching for new ways to improve the delivery of health care, innovators can make a real impact for both patients and providers. \blacklozenge

CHAIM INDIG is the founder and CEO of Phreesia.

Reinventing Health Care Services

A doctor describes his groundbreaking, transdisciplinary effort to design more cost-effective care models for conditions that drive a large proportion of US health spending.

BY ARNOLD MILSTEIN

y professional life has revolved around a single question: How can doctors and other health professionals catalyze big leaps in the quality and affordability of health care? In keeping with the Physician Charter, a modern version of the Hippocratic oath, many physicians are beginning to realize that they have an ethical imperative to promote "the wise and cost-effective management of limited clinical resources" in addition to the health of patients.

This ethical imperative has now become a fiscal imperative if the United States is to avoid what has been described in *The New England Journal of Medicine* as the "specter of financial Armageddon" for federal and state governments. In addition, US workers face a slow strangulation of job and wage growth, and employers who compete in global markets can look forward to years of declining profits.

In my work across the United States, I have observed physician groups and other health care organizations that deliver highquality care at a cost roughly 20 percent lower than average. Clinicians have the potential to push the value of the US health system to Americans far beyond today's benchmark. Evidence from the Institute of Medicine of the National Academy of Sciences suggests the possibility of even better care for at least one-third less than Americans are currently spending. But many clinicians are ambivalent about tackling this challenge.

ARNOLD MILSTEIN, MD, is a professor of medicine and the director of Stanford University's Clinical Excellence Research Center. They are not alone. Insurance companies resist competition based on the value of their services. In many markets, insurers also lack the clout to provide incentives to health care providers who approach benchmark levels of quality and efficiency. And consumers are wary of any health system change that may limit their access to care or freedom to choose providers.

In the current climate, none of the players is willing to sufficiently strengthen either the market or the regulatory mechanisms required to improve the value of care. Physicians will be important players in helping to turn around the situation, because they enjoy high levels of public trust and unique power to affect the cost and quality of health care delivery.

A BREAKTHROUGH IN CARE

To help break the stalemate, I am launching the <u>Stanford Clinical Excellence Research</u> <u>Center</u> (CERC). CERC is devoted to accelerating the discovery, demonstration, and dissemination of innovative models of health care delivery that reduce annual per capita health spending while improving health. Harnessing the power of transdisciplinary innovation will be central to our success.

A historical example may be useful here to show the impact of inventions in care models. In the 1950s and early 1960s, an imaginative physician in Baltimore named Peter Safar realized that outcomes might improve if hospitals centralized the location of their sickest patients and increased the frequency of patient observation and treatment adjustments with a dedicated team. His innovation sparked the evolution of the intensive care unit (ICU). The basic concept then spread to many aspects of hospital care, giving rise to many successful variations on the theme, such as neonatal ICUs, burn units, and surgical ICUs. Hospital mortality for the sickest patients plunged.

The concept of tailoring the design of clinical work to the needs of distinct patient groups continues to inspire hospital improvements. In 2005. I noticed that a similar intensification of care had not been tested for medically unstable patients living at home, beyond nurses' infrequent case management and generally unsuccessful disease management over the telephone. Over the past several years, I worked with Boeing in Seattle and a union-managed health benefits fund for hotel workers in Atlantic City, N.J., to test a new care model. Funded by the California HealthCare and Robert Wood Johnson foundations and designed by a team of fresh thinkers from four disciplines, we called our model the "ambulatory ICU." Our A-ICU was designed to reduce markedly the need for emergency hospital care among medically fragile patients. Early results have been impressive, and we are now testing the scalability of A-ICUs in three additional states.

CERC aims to jump-start other new care models for hospitals, as well as for ambulatory care. Each model will target an inflection point in the progression of major health conditions associated with large jumps in future lifetime spending and patient suffering. An illustrative list of such inflection points includes the nine months before and the 24 months after delivery by mothers living in poverty; the transition from obesity to morbid obesity; the first 30 days after discharge from a hospital; and the last phase of life. For example, when an obese patient progresses into morbid obesity, the total future cost of lifetime disability and care increases dramatically.

Approximately one-third of the US population is obese, and approximately 5 percent—or about 15 million people in the United States—is morbidly obese. Morbidly obese adults have seven times the risk of diabetes, six times the risk of hypertension, four times the risk of arthritis, and three times the risk of asthma as patients who are not obese. Health care for both levels of obese patients in the United States costs an estimated \$147 billion each year—or more than 5 percent of than \$30,000 on average. For this and other reasons, the rate of surgery is low relative to the number of people who are likely to benefit. If CERC selects this inflection point as a target, our goal would be a re-engineered form of bariatric surgery that lowers the cost below \$15,000, without inventing a new technology or sacrificing clinical outcomes.

Our approach is to embrace such challenges through service-design teams of five or six postdoctoral fellows in residence at Stanford University who represent the disciplines of engineering, business, social science, and medicine. Our methods will borrow the Stanford Biodesign program, which Stanford Professor of Medicine Paul Yock devised with Stanford Graduate School of Business Professor Stefanos Zenios and others to



US health care spending. A more affordable intervention that is as effective as existing treatments and reaches a large proportion of obese people approaching morbid obesity would create enormous health and financial benefits.

Today's obesity treatments based on behavior change and medication have proven woefully insufficient. Bariatric surgery, on the other hand, is quite effective. A recent employer survey shows that nearly 60 percent of public and private employers now offer some type of bariatric benefit. About 220,000 bariatric surgeries were performed in 2008, and estimates are that the number is increasing at about 20 percent per year.

The problem: The procedure costs more

adapt innovation insights from the Stanford School of Engineering's Design Program to design better medical devices.

The CERC service-design teams will initially train along with Stanford's Biodesign fellows. Training will focus on the science of innovation design. CERC will also expose the fellows to exceptionally efficient health care organizations so that the fellows design beyond today's best practices rather than rediscover what's already working. As they work, diverse faculty will mentor the fellows, subjecting their designs to rigorous review, encouragement, and intellectual challenge.

To ensure that our innovations have a ready test bed, I have recruited health care

organizations eager to experiment with highvalue service designs, such as Stanford-affiliated health systems, as well as five to six top-performing health systems outside of California. CERC will assist them in renegotiating payment methods if a new care model requires revised incentives from insurers to be financially sustainable. I have also recruited a national network of large, selfinsured employers and large health insurers to offer incentives to test the center's care models. An active focus on "value-based" payment incentives is crucial to the spread of service-model innovations in which the cost savings and the work to attain them do not naturally accrue to the same party.

INVESTING IN SERVICE INNOVATION

Although Stanford is funding CERC's startup costs, the center will need to seek additional sources of research investment. A major reason for the lack of speed in improving service design is that service innovations are at a huge disadvantage relative to patentable devices and drugs when competing for investment capital. Unlike new molecules or devices, service models are easily copied public goods. Venture capitalists and other investors turn away societally promising service investments for this reason.

Although the center hopes its models will prove compelling to today's more costfocused venture investors, we see an essential role for foundations and other social investors. Many of them are tightly aligned with CERC's mission to improve both the quality and affordability of US health care.

Just as fledgling companies benefit from their association with venture capital investors, health care design innovators need social investors. They can also play the essential role of polishing the rough edges of service innovations that designers might be too close to see. Staff from the California HealthCare and Robert Wood Johnson foundations played this role in the successful testing and spread of A-ICUs, which are now operating in dozens of US cities. Their involvement also builds interest in testing innovations among payers and providers.

Working together, CERC and social investors can ally with US health systems and payers to test and spread innovative care models. Bending the curve of per capita health-spending growth and improving clinical outcomes are a team sport.

Opportunities in Mobile Health

The United States and other industrialized countries can learn from experiments in the developing world that use the humble cell phone as a platform for innovation.

BY JASPAL S. SANDHU

ore than three-quarters of the world's 5.3 billion mobile phones are located in the developing world. These increasingly powerful devices are proving to be a lifeline for people who need improved access to health services. The trend of using mobile phones for health—known as mHealth—represents an unprecedented opportunity for improving public health.

Much of the innovative thinking in mHealth is coming from programs that target populations outside the United States, often in developing countries. Now in a twist of fate, the innovations emerging from the developing world could prove to be a significant springboard for innovation in the developed world.

IMPORTING INNOVATION

General Electric CEO Jeffrey Immelt and his colleagues coined the idea of "reverse innovation" in a 2009 *Harvard Business Review* article, proposing that big companies must innovate in developing countries like India and China to survive.¹ They argued that bringing innovations from the developing world to the developed world would both provide access to emerging markets and allow companies to pioneer new sources of profit in wealthy countries. The unique challenges of designing for low-resource environments in developing countries has fostered highly creative solutions.

One prominent example is GE's portable ultrasound device. Traditional ultrasound machines cost upwards of \$100,000, but a GE team in China designed a device for the Chinese market that plugs into a laptop and costs as little as \$15,000. The difference was not just in the product's price, but also in its target customers and uses. Instead of being designed for large hospital imaging centers and a range of uses, it was targeted to rural health clinics interested in spotting enlarged livers and gallstones. This drove further innovation in GE's imaging products, including a handheld ultrasound that retails for less than \$8,000 and is available in India and the United States, among other countries.

The Tata Nano is another example of reverse innovation. Although Tata designed the super-low-cost automobile for the urban Indian market, where it currently retails for about \$3,000, it expects to export the car to other developing countries in 2011, and it has ambitions to enter the European market by the following year.

Mobile health applications from developing countries have the same potential to penetrate developed markets. In developing countries, these applications span a wide range of activities, including data collection, disease surveillance, health promotion, diagnostic support, disaster response, and remote patient monitoring. Experts predict that much of the mHealth innovation in developing countries will center around financial incentives and payments, as mobile money services targeted at those without bank accounts expand—for example, Safaricom's <u>M-PESA</u> in Kenya and MTN's <u>MobileMoney</u> in various African countries.

Programs strengthening health care delivery and data reporting have so far made up the most publicized mHealth technologies and programs. Well-known examples include <u>TRACnet</u> (Rwanda), <u>Medic Mobile</u>, <u>MoTeCH</u> (Ghana), and <u>EpiSurveyor</u> (working around the world). A range of other services present promising opportunities for learning. (A selection of services is described on the map, "Innovative mHealth Services in Developing Countries," on page 16.)

Much of the innovative work in mobile health has emerged in South Asia and sub-Saharan Africa. The innovation in these places is a result of multiple factors, including targeted private and public funding, flourishing mobile markets, and significant health gaps. Several common themes have emerged from an analysis of the highlighted services: use of incentives or just-in-time information figures into each of these services; nearly all services involve some North-South connection between developed and developing countries; all involve mobile network operators, with roles ranging from passive communication network to active partner to service provider; and at least half have developed business models that suggest financial sustainability.

Among the applications most likely to have an impact in the United States are services that encourage positive behavior change and that remotely monitor patients. (Many of the other mHealth applications, such as those for data reporting and disaster response, do not map well to the United

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States context.) Phone-based solutions can potentially leapfrog existing approaches in the areas of behavior change and remote monitoring to lower the significant costs associated with unhealthy behaviors and with patient activity outside of clinical settings. Untapped opportunities exist to use financial or other forms of micro-incentives for behavior change, for instance. Although mobile money systems are unlikely to roll out in the United States as they have elsewhere, financial incentives do not require formal mobile money systems to function. Further, game-based approaches, such as those that <u>Text to Change</u> has developed, can be highly effective.

Although myriad mHealth programs are operating in developing-country markets, only a few prominent mHealth innovations in the United States have been imported from abroad. Among the most notable are <u>Vitality GlowCaps</u> and <u>GreatCall Medica-</u> <u>tion</u> Reminder Service, both of which are working to improve medication adherence.

The stakes are high: Not following prescribed medication instructions adds an estimated \$258 billion to \$290 billion annually to US health care costs, or up to 13 percent of total health care expenditures.² In particular, medication adherence is a major problem for the elderly, contributing to one in five Medicare beneficiaries discharged from a hospital being readmitted within 30 days.³

Vitality GlowCaps and GreatCall Medication Reminder Service do similar things, but work differently. The GlowCap device fits over commonly used prescription bottles, and it flashes and sounds when the time comes to take a pill. If the patient forgets, the product then uses an embedded wireless chip to offer a phone or text reminder, and the system can even alert a friend or family member, automatically call in a refill, and notify patients' doctors about how well they're taking their medicines. The device came several years after a similar product known as SIMpill was developed in South Africa.

A related service that works primarily through phone reminders and customer service is the GreatCall Medication Reminder Service, available as of 2010 on Jitterbug cell phones, which are designed to be particularly easy to use. The service helps the elderly remember to take all their medications at the right times. Mobile phone-based medication reminders have been used in various developing-world applications, including as early as 2001 in Cape Town, South Africa, as a cost-effective alternative to directly observed treatment, short-course (DOTS) for tuberculosis patients.

Another example is <u>Text4baby</u>, which provides free health tips to expecting mothers via text messages. Model programs such as VidaNet in Mexico and Mobile 4 Good Health Tips in Kenva provided the inspiration. With more than 190,000 users as of July 2011, Text4baby has been instrumental not only in highlighting the potential of mobile health to a broad population, but also in showing that it can operate at scale, something that has been done internationally in only a few cases. Text4baby used a publicprivate model to scale up its service, relving on a network of hundreds of partners, including financial sponsors, 18 mobile providers, government entities, and implementation partners in all 50 states to help ensure that the service can be offered free for everyone. The same approach can be seen among the mHealth programs that have scaled up globally. Many rely on complex public-private partnerships involving governments, international donors, and private entities.

None of these US programs is an exact

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copy of the global models that inspired them. This provides a lesson for organizations thinking about importing mHealth innovations. The goal should not be to copy programs exactly, but rather to adapt global innovations for the developed-world market. For instance, GreatCall's US medication reminder service does not rely on text messaging, as tuberculosis programs do in South Africa, but rather on phone calls and a Web interface. As another example, Vitality offers several other services in the United States linked to the GlowCap product, besides the remote accountability feature that defined the SIMpill product in South Africa, including refill coordination with local pharmacies and support for alerts via social networks.

Models need to adapt to the wide differences between the United States and the developing world, not to mention between the United States and other developed nations. Aside from the variations in disease burdens and health systems, many countries have different cultures of mobile phone use. In the developing world, prepaid, or pay-asyou-go, models dominate; users commonly maintain active accounts with multiple providers; people often share phones; and users do not pay to receive phone calls or text messages. All of these factors affect the design of mHealth services.

LOST IN TRANSLATION

Although the United States has seen isolated cases in which global models have been adapted, overall imports of mHealth innovation have been limited. Quite simply, the various organizations that have an interest in mHealth—government, operators, health care providers, and others—too often have not adequately examined models outside the United States. Aside from this reason, several challenges have inhibited the spread of global initiatives to the United States, including a lack of evidence, unclear regulation, payment mechanisms, and market failures.

Lack of Evidence The field is missing evidence of improved health outcomes, both globally and domestically. Early mHealth programs rarely included strong measurement components. A lack of evidence of impact on health behaviors or outcomes will prevent policymakers and many decision makers from investing in new technologies and programs at a significant scale. The good news is that the evidence is beginning to appear. Late 2010 saw the publication of

Innovative mHealth Services in Developing Countries

HealthLine Bangladesh

Runs a fee-based medical call center available 24 hours a day to Grameenphone subscribers.

mDhil | India

Broadcasts health messages on a subscription basis. Surpassed 150,000 paid SMS subscribers in 2010.

Sproxil Nigeria

Establishes a pharmaceutical anti-counterfeiting system in which products have item-unique codes that customers can text to a specific number to ensure that the product is genuine.

Text to Change | Uganda

Provides incentive-based interactive text messaging in the form of multiple-choice questions. Encourages health education, counseling, and testing for HIV/AIDS.

two notable randomized controlled trial studies of text and mobile phone programs, and both showed significant improvements in outcomes. The first, the WelTel system in Kenya of text messages to help HIV patients stick to their medications, showed significant improvements in drug adherence and rates of viral suppression among those who used the service.⁴ The second study focused on WellDoc in the United States, and it examined a more comprehensive mobile phonebased diabetes management system for type 2 diabetics. It showed statistically significant improvements in blood glucose control levels among users of the WellDoc system.⁵ In addition, the Text4baby program is undergoing six independent studies, but the earliest data are not expected to be available until the end of 2011. Moving forward, the field needs for evidence to be gathered quickly and for both positive and negative outcomes to be shared.

Unclear Regulation One thought leader interviewed during the course of this work suggested that strict domestic regulation is leading to the "export" of mHealth innovation. The framework for wireless health from the US Food and Drug Administration (FDA) is evolving, and it remains unclear how these advances will be regulated. The <u>mHealth</u> <u>Regulatory Coalition (MRC)</u> is advocating for greater clarity around regulatory issues so companies and investors can better plan for and fund innovation. The MRC is producing a guidance document to assist the FDA in formulating a reasonable approach to regulating mHealth technologies. It released the

Changamka Kenya

Allows patients without health insurance to save for health care expenses using a medical smart card combined with the Safaricom M-PESA mobile phone-based money-transfer services. Savings are redeemed for health services at pre-negotiated rates.

Project Masiluleke | South Africa

Appends information about HIV and tuberculosis help lines to "please call me" phone messages. More than 600 million messages sent.

first part of this document in May 2011, with the final draft to be presented to the FDA in fall 2011. Many of the issues surrounding mHealth regulations are unlikely to be resolved before the end of 2011.

Payment Mechanisms Health programs in the United States often look to payers—generally employers and insurers, both public and private—to support new services. But US payers have not shown an interest in purchasing mHealth solutions. To be successful in the United States, mHealth applications might have to appeal to a new group of payers, including consumers, health care professionals, facilities, and industry players like pharmaceutical companies. Multiple stakeholder groups might also collaborate to pay for a single service.

Market Failures In most developing countries, governments sponsor mHealth programs and fund strong public health programs. In the United States, an employerbased system prevails, and so market failures frequently hamper the development of services that can deliver impact but for which private payers see no clear return on investment. Innovations in public health and prevention often stall out for these reasons.

LESSONS FOR THE FIELD

Based on extensive research of the existing literature and conversations with thought leaders and practitioners in the field, several lessons have emerged about how mobile health might become an area of successful reverse innovation.

Go Beyond Apps Much of the current focus on mHealth in the United States is on smartphone applications, with a rapidly increasing interest in embedded wireless devices, such as those for in-home patient monitoring.⁶ But in the rest of the world, products and services rely heavily on text messaging and voice. The past five years in the United States have seen a rapid adoption of text messaging. According to Nielsen, people under the age of 18 send or receive an average of 2,779 texts per month. On the other end of the spectrum, those over age 65 exchange 32 texts per month, still many more messages than in past years. These numbers suggest an opportunity for text messaging solutions. In addition, voice communications have been used for largescale health hotlines in Mexico and India. and interactive voice-recognition systems have supported community health workers in Pakistan.⁷ Although smartphone applications might represent the bleeding edge, simple text and voice represent powerful tools with almost ubiquitous reach.

Target the Underserved In the United States, the underserved are described in various ways: the rural and urban poor, the uninsured, the underinsured, the Medicaid population, and the undocumented. Underserved US markets often provide opportunities for a more direct mapping of applications from developing countries, particularly those from Africa and South Asia, given that mHealth programs often target the poor or those who serve the poor. Like poor populations in developing countries, the underserved in the United States are more likely to use prepaid mobile phone plans, share technology, rely on voice and text over data, and own more basic handsets. Effective programs, particularly those that emphasize behavior change, understand the culture of their users.

Engage Smaller Operators The largest US network operators—AT&T, Verizon, and Sprint—have all indicated an interest in exploring their roles in mHealth over the coming years. These three operators support 250 million users, not including the pending merger of AT&T and T-Mobile. Nevertheless, they do not target specific markets of the underserved—urban youth, the elderly, and immigrant communities—like the providers that focus on prepaid services. Among the largest operators with the prepaid model in the United States are Cricket

Communications, Boost Mobile (Sprint), MetroPCS, and TracFone. Smaller operators like these could provide mHealth services to their customers as something that adds value, and in the process they could attempt to increase usage of voice and data services. Developing countries have already seen this happen. Many operators have recognized that providing value-added services is one of the most effective ways to retain customers in a hypercompetitive business without service contracts. Examples of such services include mobile money services; HealthLine from Grameenphone, Bangladesh's largest mobile network operator; and life insurance with the purchase of a SIM card, a product that both Tigo and MTN have launched in Ghana. Just as in the developing world, mobile health services have the potential to build and retain customers among smaller providers in the United States.

Mix Digital with Tactile The next generation of innovations in mobile health will not rely just on the point-to-point communication capabilities of phones. Rather, they will integrate the digital with offline products and services as well. For example, the <u>X Out</u> TB service, from a team of developers at MIT, deploys a specially designed urinalysis test strip with embedded numbers that are revealed only when patients who have taken their tuberculosis medications take the test. The numbers in turn unlock secure mobile phone credits, a novel micro-incentive. Similarly, Sproxil works with pharmaceutical companies to print a unique physical code on the label of each product. Consumers can text the code to a specified number in order to ensure that the product is genuine before they make a purchase. A 2010 study found that 70 percent of Nigerian antimalarial and antituberculosis drugs were ineffective, either because they were counterfeit or because they did not have a high enough dose of the active ingredient. Both X Out TB and Sproxil offer inspiration for developed-world services that mix the digital and the tactile to create the next wave of mHealth innovation.

Completely Rethink Business Models Fundamental innovation requires new approaches to revenue generation. For example, many of the innovations coming online in developing countries will be linked to mobile money services. <u>Changamka</u> uses smart cards and the Safaricom M-PESA mobile money service to help Kenyan women save for safe pregnancy and delivery services. The United States does not have a strong culture of patients directly purchasing health services, as is common in the developing world, but the Changamka model has the potential to fuel any number of breakthroughs.

LOOKING FORWARD

International markets offer an important source of learning for developed countries. The technologies and business models emerging in developing countries have been introduced in low-resource settings to improve health care access and quality. These approaches have already begun to inspire mHealth innovation in the United States and other developed countries.

Some of this learning will be based on existing models, but much of it will borrow from innovations that have yet to be launched. Direct translation will remain elusive. Throughout the process, the adaptation of successful models to industrialized markets will require creativity, flexibility, and a deep understanding of the people who use emerging technologies. \blacklozenge

The following people were interviewed for this research, which was supported by the California Health-Care Foundation: Aman Bhandari, US Department of Health and Human Services; David Haddad, mHealth Alliance; Brad Houser and Larry Atwell, Cricket Communications; Don Jones and Ryan Gorostiza, Qualcomm; Ashok Kaul, Wireless-Life Sciences Alliance; Patricia Mechael, Columbia University; Paul Meyer, Voxiva; Douglas Naegele, Infield Health; Josh Nesbit, Medic Mobile; Mitul Shah, West Wireless Health Institute; Al Shar, Robert Wood Johnson Foundation; Rodrigo Saucedo, Carlos Slim Health Institute; and Dane Stout, mHealth Regulatory Coalition.

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Government 2.0

Thanks to Todd Park, a federal agency has discovered that health care organizations can think more like nimble startups than like lumbering giants.

BY CARLEEN HAWN

he great irony of the transformative health care reform legislation passed in 2010 is that although the law promises access to care for 30 million Americans, it relies on an outdated structure woefully ill prepared to serve them. Constrained resources, flawed economics, rising costs—how can a health care system under so much strain survive such an expansion? The answer will be found in creativity.

Over time, the most dynamic health care institutions have boosted their creative metabolisms, so to speak, with promising methods for vetting new ideas and technologies. More recently under Chief Technology Officer Todd Park, the US Department of Health and Human Services (HHS) has become known as a budding innovator, too—and none too soon, given the magnitude of the challenge it confronts.

Like all institutions in this era of reform, HHS is leveraging the entrepreneurial experience of people like Park to reinvent how it does business. But as Park explains, HHS is aiming for more: "We are trying to do things in government that will facilitate entrepreneurship and innovation in the private sector. Think of it as *meta-entrepreneurship*."

The department can be thought of as the largest, most important health care institution in the country. As the agency that administers Medicare and Medicaid, it in effect picks up more than 47 percent of the nation's health care tab. Private insurance companies also look to the HHS for benchmarks that help them establish their own pricing. And the department's newly created <u>Centers for Medicare & Medicaid</u> <u>Innovation</u> is now responsible for creating new payment models, such as systems to pay physicians' salaries instead of fees for service. HHS plays an equally significant role as a health care regulator, too.

What happens at HHS will therefore help shape the course of the entire industry. As they endeavor to create a culture of innovation inside and outside the government's bureaucracies, Park and his colleagues are learning important lessons for the field.

AN ELEPHANT LEARNS TO DANCE

When Silicon Valley entrepreneur Todd Park joined HHS as chief technology officer (CTO) in August 2009, the department was the least likely of government institutions to be described as nimble or creative. It certainly did not look innovative. As the health reform debate reached a crescendo, HHS was more often described as a bloated elephant.

Part of this perception owed to its size. HHS is a colossus, housing 10 of the nation's major domestic policy administrations, including three of its largest: the Centers for Medicare & Medicaid Services, the National Institutes of Health, and the Administration for Children and Families. HHS has 73,000 full-time staff, which is roughly equivalent to the payroll of Cisco Systems. It also has an authorized annual budget of \$902 billion. Its spending authority is 50 percent larger than the 2011 general funds of all 50 states *combined*.

Big bureaucracy was foreign territory to Park. He had captured the Obama administration's attention as the co-founder of Athena Health, an early health information technology startup specializing in revenue cycle management for medical practices. When Athena Health debuted on the NASDAQ stock exchange in 2007, the then 34-year-old Park became a multimillionaire and an instant symbol of Silicon Valley success.

Back in fall 2009, it was far from certain that Congress would pass a health reform bill. But Park's move to HHS hinted that the department was about to undergo some

The modus operandi is to come up with an idea, find three to five people and form a virtual startup around them, and run it like a Silicon Valley operation.

radical change of its own. To start with, until Park agreed to become its CTO, the job had never existed at HHS. It turned out that Park's superiors, HHS Secretary Kathleen Sebelius and Deputy Secretary William Corr, had an unusual take on the new role.

"When I got here my boss told me, 'Todd, you're a change agent, and your job is to originate initiatives that will help HHS harness the power of data and technology in innovative ways to improve health," Park recounted in an interview. This was not the traditional CTO mandate. "The title is a bit of a red herring—I'm really an entrepreneurin-residence," Park explains, slipping into his Silicon Valley dialect.

An entrepreneur-in-residence, or EIR, works under the tutelage of a venture capital firm and is typically expected to source new deals, form a new company, or help manage an existing company in the firm's portfolio.

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Inside a bureaucracy as complex as HHS, succeeding as its lonely EIR was prone to be even more difficult than managing its IT systems might have been. But Park had little time to dwell on this fact.

A lesser-known mandate of the health reform bill of 2010 was a requirement that HHS build a consumer service that could help consumers "take control of their health care." The goal was to make information more accessible to average Americans.

It was a vague but daunting objective. To put a finer point on it, the law *required* that a new Web portal provide details about prices and it shall allow any American who walks up to it to get all the information on every insurance company in America—and good luck!"" In perfect bureaucratic form, Park's HHS colleagues didn't actually expect him to deliver it. "They expected us to launch with a placeholder [site]," he says.

By the time they set to work, Park's team had just 75 days to launch the portal. On July 1, 2010, HHS debuted <u>HealthCare.gov</u>, and it was anything but a placeholder site. Consumers found an intelligent engine that, on the basis of responses to a few questions, could deliver a customized overview of in-



and coverage for every public or private insurance plan on the market. The portal should also explain confusing topics like tax credits and reinsurance programs to small businesses, and it should educate consumers about how the labyrinthine insurance industry works. Later it would add preventative care advice, too. To a technology entrepreneur, the product might have been described as a Yahoo! for health insurance.

Only days after Congress passed the Patient Protection and Affordable Care Act to reform the health care system, the task of building such an all-encompassing portal landed on Park's desk. Sebelius gave her new CTO just three months to build it. Even by Silicon Valley's adrenaline junkie standards, three months to get from concept to launch was extremely tight.

"No one thought we could do it," Park says. "It was like, 'There shall be this site surance plans. They could toggle through Web pages to compare thousands of plans for their benefits, participating providers, and eligibility requirements. The portal was also interactive, regularly asking users how HHS might improve the site.

The response was a groundswell. Since it launched, 5.7 million people have visited HealthCare.gov. If simple when compared with inventing a faster microchip, the portal is nevertheless an innovation that has helped transform HHS from a remote bureaucracy into an accessible presence in the lives of millions of newly engaged health care consumers.

FIVE RULES FOR INNOVATORS

Building successful innovation projects like this inside such an unlikely institution, and in so short a time, wasn't an accident. Park has developed a tried-and-true set of rules that guide his work.

"I wouldn't say we have a system yet, but there are things we are doing that are meant to be systemic," Park says. He breaks down his method into the five standard operating procedures that follow. (See "Todd Park's Rules for Innovators" on page 20.)

RULE #1: Downsize Your Idea Step one is to decide on the right projects to pursue. Park uses an easy-to-remember, two-part filter: First, the project must have the potential to generate a significant impact that furthers the organization's mission. Second, the project must be small enough for just five people to tackle.

"Start with the institutional mission or the high-level goal," says Park, "and then ask yourself: What are the [individual] things most likely to produce a big 'delta' against that goal?" The smaller things with the largest mission impact are the projects you should take on.

At HHS, the high-level goal was to help consumers take control of their health care using technology and data—again, a mission both vague and grand. The information portal, however, was a comparatively small idea that had the potential to deliver a lot of bang for the buck in advancing the high-level goal. It was also much simpler to execute than, say, a full-scale software application, which would have required a more complicated information technology architecture, much more code, and many more people.

RULE #2: Form Small Teams Once you've downsized your grand mission into a realistic project, form a core team of no more than five people. Call it "The Rule of Five." Go larger than five, Park cautions, and the incremental costs of full-time employees outweigh the benefits of the teamwork. "You just cannot get more than five people to think like a single brain," Park says. Core teams of 10 or 20 are simply too big to think collectively or to track what's going on.

Now, Park doesn't think that groups of five can accomplish everything. Some projects need worker bees to get things done. For example, Park added 15 researchers to pull together the data about insurance plans for the portal. Park thought of them as contractors, but he confined ownership over the project to a core unit of five, including himself.

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Projects also need the right mix of people. People outside the Beltway know that the best way to organize an innovative effort is to have the strategy people, the technology people, and the operations people all blended together on one team. "Employees one through five should be really hard to tell apart," Park says. "They are all like [Navy] SEALs—people who can be called upon to do any of the necessary tasks. They are always in the same room, and they are all focused on the same question: 'What does the customer want?'"

RULE #3: Spend Time with Your Custom-

ers When first asked to explain his methods at HHS, Park responded tartly: "I can tell you what we didn't do. We didn't do a focus group!" Instead Park and his team spent their time conducting "deep dive" conversations with real people.

Big organizations often hire consultants and market researchers to compile enormous research reports. Park believes that innovators are better served when they skip expensive, formalized research and instead spend lots of time asking customers questions like "Would you use this product?" and "Do you like it better this way, or that way?"

People cannot want what they do not yet know. "A focus group would never have come up with the Internet or e-mail," Park says. "All the focus groups in the world will not help you discover the customer's *inarticulable preference*." He says focus groups are great for assessing incremental improvements to existing products, but they are useless for identifying opportunities to create breakthrough innovations that people don't yet know they desperately need.

RULE #4: Identify the Minimum Viable Product Innovators commonly make the mistake of trying to do too much, too soon. They try to build a space shuttle instead of a glider. Finding your "minimum viable product" means building the smallest possible offering that will still deliver value to the customer.

"The probability that your first idea is the right idea is incredibly low," says Park. Athena Health's first business plan was to manage medical practices. But this wasn't the product that doctors needed. Doctors really wanted a smarter, easier way to collect payments from insurance companies, so Athena Health transformed itself into a provider of revenue cycle management services.

Knowing that the first product is likely to be insufficient, Park recommends instead going to market with a stripped-down offering that your customers can begin to use right away. Then collect feedback—and

iterate, iterate, iterate to improve the product from there.

This approach also reinforces Rule #2. When you engage customers early in the process, you increase the odds of delivering what they need, which increases the odds of success.

RULE #5: *Impose Deadlines of 90 Days or Less* If inertia is the enemy of the incumbent, urgency is the innovator's friend. The best way to sustain a sense of urgency, Park says, is to impose deadlines on your project of 90 days or less.

Imposing short deadlines gets you to market sooner, which gives you an earlier chance to uncover and fix your product's shortcomings. Aggressive deadlines also have the added benefit of enforcing discipline. When a team has just 90 days to show results, it is less likely to let anything distract it from that goal. The team can achieve incremental progress as well, which keeps everyone motivated.

If you think your project requires more time to launch, you haven't thought small enough. Go back to Rule #1.

THINK SMALL, DEMAND SPEED

You may have noticed a pattern here. All of Park's five operating procedures are mutually reinforcing. In the end, they come down to achieving bite-size yet outsize results quickly. They have nothing to do with the physical environment your team works in, or with the technology tools they use. "Just putting [your staff] in a building with translucent walls and giving them iPads isn't going to make them innovative," says Park. But by following his guidelines, the process of innovation itself can be scaled.

Since building the health care portal, Park has gone on to lead even larger projects successfully. For instance, the <u>Com-</u> <u>munity Health Data Initiative</u> (CHDI) is a

Todd Park's Rules for Innovators

- 1. Downsize your idea.
- 2. Form small teams.
- Spend time with your customers.
- 4. Identify the minimum viable product.
- 5. Impose deadlines of 90 days or less.

public-private program to help local leaders and public health workers more clearly understand, and improve, the performance of their community health systems. Web tools mine HHS data on the regional use of resources, rates of avoidable hospitalizations and readmissions, the prevalence of diseases within communi-

ties, and the determinants of disease, such as access to healthy food.

The project originated as a plan to build, in-house, the largest-ever health data map. Park and his team quickly realized their original goal was too big to be a glider, to borrow his catchphrase. HHS released the data to the public and let outside coders do the heavy lifting instead.

Next, Park expanded the CHDI project into a national <u>Health Data Initiative</u> (HDI). Another joint effort between HHS and the private sector, HDI aims to spur entrepreneurs to develop consumer software and smartphone applications that tap into government health care data. Once secreted away in hidden databases, these data troves are also now available to anyone at HHS affiliate websites like Health.Data. gov and HealthIndicators.gov, and through sites operated by private sector partners like Health 2.0.

In the last year, Park has sponsored HDI "code-a-thons" in San Francisco, Boston, and Bethesda, Md., working together with Health 2.0. Hundreds of developers have produced dozens of new tools, including 45 applications that Park claims "present real, viable business models."

As it both innovates internally and fosters public-private projects like these, HHS is setting its sights on a transformation of health care. Its work, in turn, demonstrates valuable lessons for entrepreneurs in all environments.

"It is absolutely possible to innovate in a way that is replicable," Park concludes. "The modus operandi is to come up with an idea, find three to five people to make it real, form a virtual startup around them, and run the thing like a Silicon Valley operation. This is the polar opposite of how large companies function. It is anathema to how government functions. But if HHS can do it, anyone can do it." \blacklozenge

Foundations as Investors

Social investors are experimenting with a profusion of creative funding mechanisms to help innovators sustain health-improving approaches and to achieve greater impact.

BY JOHN GOLDSTEIN AND MARGARET LAWS

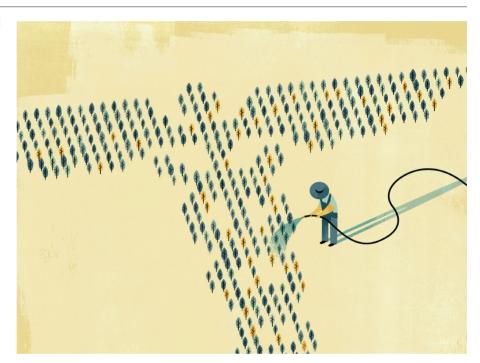
ifewave was facing an inflection point in late 2010. The early-stage company had a technology promising more accurate fetal monitoring in obese and overweight women, whose deliveries now account for 60 percent of all births in the United States. These women have pregnancies with high rates of complications and C-sections.

Early <u>Lifewave</u> clinical trials had produced promising results. Technology experts, investors, and clinicians also viewed the product favorably. But the company was having difficulty raising the necessary funds to get through the regulatoryapproval process.

The California HealthCare Foundation (CHCF) was contemplating an investment through its Health Innovation Fund. If a CHCF investment were to be successful in moving the company to the commercialization stage, the Medicaid program in California, which pays for half of the pregnancies in the state, could reap significant savings.

Lifewave was the Innovation Fund's first for-profit investment proposal. The foundation team began with a review of the company and its "mission fit" with CHCF's charitable goals. The CHCF staff engaged in a spirited discussion about whether and how this investment could drive lower-cost care and improve access for underserved populations, its criteria for investment. Once the proposal passed the mission-fit

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screen, the team would finalize the terms of the investment, in consultation with legal and investment advisors experienced in both technology investment and foundation impact investing.

In order to secure an investment from CHCF that could help get it through regulatory approval, particularly given the challenges the company had faced seeking capital from traditional investors, Lifewave was prepared to adhere to the foundation's investment goals—to improve outcomes for obese and overweight pregnant women, the providers who care for them, and the publicly financed system that pays for much of the care they receive. After approximately four months of due diligence, CHCF invested just under \$1 million in April 2010.

The foundation is among many organizations looking for ways to enhance traditional approaches to funding social innovation. What drives their entry into "impact" or "mission" investing varies, but it generally includes a desire to scale up and spread successful programs, align an investor's assets with its mission and goals, and work with innovative efforts across the spectrum of nonprofit and for-profit organizations. Several US health care foundations are following in the footsteps of their philanthropic counterparts in housing, economic development, and education. They are developing ways to find, make, and manage financial investments in private sector companies that can help fulfill their charitable missions.

This article focuses on foundation investments as a representative sample of the wider realm of social investments with a market orientation.

THE BASICS OF MISSION INVESTING Mission investing, often referred to as

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impact investing, refers to investments in revenue-generating nonprofit and for-profit organizations whose work is consistent with an investor's charitable purpose and goals.¹ The emphasis is on *investments*, as opposed to grants. Unlike traditional grantmaking, mission investors expect that the funds will be paid back—recycled for their charitable purposes, so to speak. These investments offer investors a way to advance their philanthropic missions while supporting enterprises that may be more likely to achieve sustainability and scale than the typical grant-funded initiative.

Mission investments can include cash deposits, bonds, loans, or venture capital and private equity investments in companies, and they can be made directly, through funds, or via specialized intermediaries. Some mission-investing programs are market-oriented, generating financial returns that are comparable with typical investments in an organization's portfolio. Within the foundation world, these are typically referred to as mission-related investments (MRI). Other programs take more risk or accept lower returns than commercial investors would take, but they also have the potential to generate significant impacts and deep alignment with an organization's mission. These investments are a subset of mission investing referred to as program-related investments (PRIs). With all forms of mission investments, foundation social investors follow specific standards and regulations.

Social investors are exploring mission investing because they have experienced "successful" pilot projects that never made it beyond the initial site and often didn't continue once the grant period was over. Although grants are the right tool for much of the work of social investors, fundamental limitations and challenges exist to scaling and sustaining organizations whose primary "fuel" consists of grants.

Moreover, many of the innovations that social investors care about are in the forprofit sector. This dynamic is particularly true in health. Whereas government pays for about 47 percent of health care delivered in the United States, private sector institutions deliver the vast majority of health care using technologies, devices, and tools that for-profit companies develop. In part because of health care cost escalation, health reform, and other forces, experienced innovators and investors are increasingly focusing their energy, capital, and creativity on developing solutions that ensure highquality, lower-cost health care, as the articles in this supplement have demonstrated.

This growing pool of innovation and capital creates an exciting opportunity for social investors to reach out to new partners who can help tackle important health care challenges. These investors now have the opportunity to align their own knowledge and assets with this emerging breed of entrepreneurs and investors. In addition, the long history of health foundation work with the Medicaid and Medicare programs and public hospitals offers a window into what it will take for innovative technologies and services to be successful as these public programs expand and evolve under health reform.

IMPACT INVESTING IN HEALTH CARE

What follows is a map of the emerging impact investment landscape among US health care foundations. The goals and approaches vary significantly, but the diversity among programs provides a sense of how those seeking to use investments to improve health have approached mission investing.

Interest areas extend beyond health care delivery to include the social factors that affect health (referred to as social determinants of health), such as poverty, education, air quality, and wellness issues like food and fitness. Opportunities for investment in both for-profit and revenue-generating nonprofit organizations exist in each of these areas, and each can offer social investors interesting opportunities to extend their traditional approaches to grantmaking and endowment management. (See "Areas of Mission Investment" at right.)

Although health care foundations are working across a wide range of topic areas, impact investment projects are beginning to emerge under several common themes.

Lowering Investment Risk Foundations can play an important role in lowering the risk for traditional financial investors, as the authors argued in the article that opened this supplement. (See "Funding the Safety Net" on page 4.) Their work can encourage investors—whose capital, expertise, and networks offer significant benefits—to support initiatives that might not otherwise meet the criteria for investment.

For example, The California Endowment (TCE), in collaboration with financial intermediary NCB Capital Impact and a diverse range of partners, established the <u>California</u> <u>FreshWorks Fund</u>, a public-private partnership loan fund created to increase access to healthy food in underserved communities, spur economic development that supports healthy communities, and inspire innovation in healthy food retailing.

In California, adults in neighborhoods with low access to healthy food options are 20 percent more likely to be obese than those with high access to healthy foods. The goal of the fund is to support supermarkets and other fresh food outlets in the "food deserts" of low-income communities. Through the fund, TCE and other social investors provide forms of debt and credit that remove some of the risk to commercial lenders and encourage them to provide major financing to projects.

Funding Specialized Financial Products Several intermediaries, including some that operate largely in traditional markets,

Unlike traditional grantmaking, mission investors expect that the funds will be paid back—recycled for their charitable purposes, so to speak.

have worked in conjunction with foundations to create specialized financial instruments with significant health impact goals.

The W.K. Kellogg Foundation partnered with Community Capital Management, an experienced fixed-income manager, to find and purchase market-rate "community food bonds" that finance community facilities, schools, and community groceries. Inadequate access to healthy food in low-income communities and schools creates a critical impediment to good health, so the goal was to increase the supply of healthier, affordable food for vulnerable kids and their families.

Specific bonds supported a community garden where residents in an affordable eldercare center in Michigan could grow their own food; upgraded school lunch facilities to enable from-scratch meal preparation in a low-income school district in New Mexico; and an expanded facility for the Greater Boston Food Bank.

Establishing the Business Case

Recent advances in computing power, mobile technology, and networking have made possible an explosion of innovation that helps people track and manage chronic diseases more effectively. Although there is general agreement that these innovations can improve health, the business models necessary for them to reach sufficient scale have not been established. Social investors have an important role to play in developing the return on investment (ROI) cases—through studies, pilots, and business model development—that are necessary for new,

cost-saving technologies to gain traction.

As one example, CHCF made a recoverable grant for a pilot with <u>Asthmapolis</u>, a company with a global positioning system that tracks where asthma episodes occur. The service allows asthma sufferers to manage their treatment more effectively, and public health workers to better understand the environmental triggers that exacerbate symptoms and contribute to health care costs. As part of this effort, CHCF and Catholic Healthcare West will be working with the company and its pilot partners to demonstrate cost reductions due to the technology and to explore business models with a range of payers and providers in the commercial, safety net, and government sectors.

Moving Innovation into New Markets Traditional financial investors and their portfolio companies first seek to gain a foothold in the most profitable markets. This often leaves large but less lucrative markets, such as Medicaid patients or rural areas, without sufficient access to innovations. Social investors can create the financial cushion to test innovations and take them into traditionally underserved markets. Foundations in particular can play a crucial role in investment syndicates as strategic investors and intermediaries to help safety net providers and commercial companies work together more effectively.

Small and rural hospitals often cannot attract or afford qualified staff to supervise their pharmacies 24 hours a day. Avoidable medication errors are the result. <u>Pipeline Healthcare</u> (PHC) offers "tele-pharmacy" services that provide expert, remote supervision for these hospitals. The company is able to share a single pharmacist among several hospitals, increasing efficiency and

Areas of Mission Investment	
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Health Care	Health-care delivery IT and administration Drugs, devices, and diagnostics Organizing and optimizing care
Wellness	Food and nutrition Fitness Wellcare
Social Determinants of Health	Family economic security Community infrastructure and social supports Environmental health

improving compliance.

CHCF is contemplating an investment in PHC as part of a syndicate that includes the foundation, an investment firm, and a technology company. Through the venture, CHCF would help hospitals that care for underserved Californians to lower costs and improve clinical outcomes, and PHC hopes to prove its cost-reduction case and value to safety net providers.

Facilitating Lending One of social investors' simplest tools is below-market-rate loans to help health care organizations fulfill their charitable missions. Foundations across the country have provided working capital and construction loans to clinics that serve low-income people, at rates below what they would have been eligible for from traditional lenders. The loans allow community health centers to devote more of their resources to serving people in need.

For example, the California Primary Care Association (CPCA), in partnership with financial intermediary NCB Capital Impact, created the Emergency Working Capital Loan Fund in 2008. CPCA launched the program when a state budget crisis resulted in payment delays to community health centers that serve people on the state's Medicaid program, Medi-Cal, which is the primary source of revenue for these clinics. California clinics were eligible to apply for up to \$250,000 to cover working capital needs as they waited for payment. Clinics return the funds as soon as Medi-Cal pays, typically within two to three months.

Participants in the fund have included CPCA, Sutter Health Systems, Catholic Healthcare West, the Nonprofit Finance Fund, the Mercy Partnership Fund, and the California HealthCare Foundation. All the organizations have made funds available at rates ranging from 1 percent to 5 percent. When loans are blended together according to the proportion the funders have lent, the interest rate to the borrower becomes 3.25 percent, well below market rates. The fund has been renewed most years since 2008, and its total capital has ranged from \$20 million to \$30 million. The funding partnership will be expanded this year to include several new participants, including two foundations. NCB Capital Impact continues to do all the loan underwriting and servicing, and together with CPCA has created a loan rantee fund to mitigate the risk of late

guarantee fund to mitigate the risk of late repayment or default.

Another example is <u>Playworks</u>, a national nonprofit that has developed a program to bring recess back to public schools. As public school budgets are cut and recess is removed from the school day, safe and engaging play is disappearing from the lives of many children. With significant grant funding from the Robert Wood Johnson Foundation (RWJF), Playworks expanded from its original base in Oakland, Calif., to more than 250 schools in 15 cities. Even with the grant funding. Playworks still faced a significant working capital deficit, because its payments often came well after the organization had incurred expenses. RWJF partnered with OneCalifornia Bank to meet this working capital need through a deposit that the bank used as collateral against which to administer a loan to Playworks so that it could "keep recess going" while waiting for school funds to come in.

LOOKING FORWARD

These are just a few of the ways that the tools of impact investing can improve health care. They represent creative thinking and a willingness to cross long-established boundaries between sectors in the pursuit of common goals. As the United States seeks to reform its health care system to both lower costs and improve access, such collaboration is vital. Foundations and other social investors have an important opportunity to serve as strategic partners in supporting the brightest and most creative entrepreneurs in creating lower-cost and more accessible models of care. \blacklozenge

For a more extensive definition, taxonomy, body of examples, and discussion of regulatory requirements, see Grantmakers in Health, "Guide to Mission Investing," May 2011.



CALIFORNIA HEALTHCARE FOUNDATION

The California HealthCare Foundation (CHCF) works as a catalyst to fulfill the promise of better health care for all Californians. We support the ideas and innovations that improve quality, increase efficiency, and lower the costs of care.

Through its Innovations for the Underserved Program, the foundation supports entrepreneurs pursuing new business models with the potential to significantly lower the costs of care or substantially improve access to care. Visit <u>innovations.chcf.org</u> to learn more about our grants and investments.

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