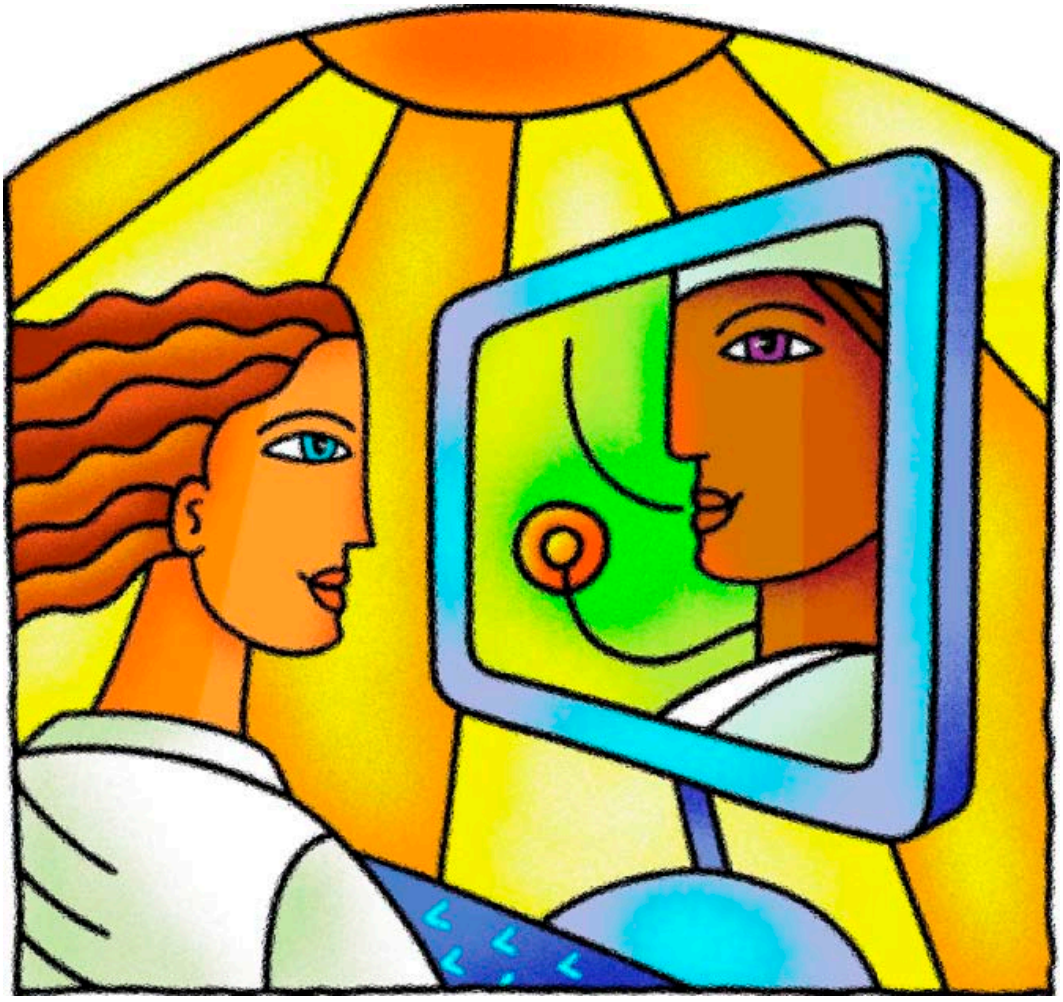
California HealthCare Foundation



Health Care Without the Doctor:

How New Devices and Technologies Aid Clinicians and Consumers

May 2009

Health Care Without the Doctor:

How New Devices and Technologies Aid Clinicians and Consumers

Prepared for

California HealthCare Foundation

by

Mary Kate Scott, M.B.A.
Scott & Company, Inc.

May 2009

About the Authors

Mary Kate Scott is the principal at **Scott & Company, Inc.,** a consulting firm in Marina del Rey, California, that specializes in health care strategy.

About the Foundation

The **California HealthCare Foundation** is an independent philanthropy committed to improving the way health care is delivered and financed in California. By promoting innovations in care and broader access to information, our goal is to ensure that all Californians can get the care they need, when they need it, at a price they can afford. For more information, visit www.chcf.org.

Contents

I. Executive Summary

The trends described in this report could potentially increase the health care system's capacity and thereby create greater access to care while reducing costs and improving health outcomes.

ACCESS TO HEALTH CARE, THE QUALITY of care, and rising costs are perennial issues that in recent years have spurred new means of delivering services. One notable evolution has been a shift in diagnosis, monitoring, and treatment from physicians to mid-level clinicians and consumers, offering less costly and more convenient options. Innovative technologies, regulatory changes, and consumer interest are major factors driving this shift. The technologies include simple, accurate, and inexpensive tests and devices for a wide range of medical conditions, and online search, information, and interconnectivity. The trend could potentially increase the health care system's capacity and thereby create greater access to care while reducing costs and improving health outcomes.

The shift has important implications for health care providers, payers, device manufacturers, policymakers, and consumers. Among them are the impact on health outcomes, the safety and design of devices, cost and reimbursement issues, and the response of mainstream health care.

This report discusses the technologies, regulatory trends, and market forces that are reshaping the way many types of health care are delivered, and what the shift in diagnosis, monitoring, and treatment to mid-level clinicians and consumers means for stakeholders. It also presents key questions for further discussion and research.

II. Overview

New technologies, regulatory changes, and trends such as consumers' desire to achieve better health outcomes and take more control of their health are the major forces spurring simplified diagnostic and monitoring tools.

THE LAST 30 YEARS HAVE SEEN REMARKABLE CHANGES in the way medicines are prescribed and consumers' health is assessed and managed inside and outside the doctor's office. Nurse practitioners have much greater prescribing authority, consumers can purchase more than 700 over-the-counter (OTC) medications whose ingredients and dosages were once available only by prescription, and, in the last 15 years, numerous OTC devices have become available that enable a nurse, technician, or consumer rather than a physician or laboratory to diagnose or monitor a medical condition.[1]

These devices can identify a particular condition, help manage it, or assess general health. When they first arrived on the market, physicians ordered and administered them. Over time, however, doctors prescribed the devices for use by others, and ultimately they became available for OTC purchase. Pregnancy and cholesterol tests are good examples of this evolution.

The technologies fall into three broad categories:

- Those that were once viable only in a doctor's office or diagnostic laboratory and are now available for use in a lower acuity setting, such as a clinic or home;
- Algorithms that draw upon evidence-based medicine to guide clinicians when they treat patients; and
- Online search, information, and interconnectivity.

Some of the most popular technologies are those that screen for pregnancy or narcotics, monitor blood glucose levels, diagnose urinary tract infections, treat sleep apnea, enable online support for patients, and help consumers manage their personal health data through online health records, calendars, and trackers.

According to one forecast, the worldwide point-of-care testing market, which includes tests that health care professionals or consumers perform, will grow from $10.3 billion in 2005 to $18.7 billion in 2011.[2] The number of mid-level clinicians and consumers using diagnosis and monitoring technologies also is likely

to increase as more technologies become available and more people opt for simpler health care or self-care that supplements or replaces other alternatives. For example, by 2010 the global market for home blood pressure monitors will have grown at an estimated annual rate of nearly 7 percent in the previous three years to more than $1 billion.[3] The $7 billion market for home glucose monitoring has been increasing at an annual rate of 12 percent to 18 percent.[4]

The expansion of diagnostic, monitoring, and treatment technologies could be an enabler of home health care. One in five adults, or 44 million Americans, provides unpaid care to another adult.[5] The U.S. Bureau of Labor estimates that the number of home health care aides will increase from 1.5 million in 2006 to 2.3 million by 2016, making this one of the fastest growing occupations. Reasons for the anticipated growth include the increasing demands of an aging population and rising health care costs. The average cost of home care provided by a home health aide is about $6,000 per patient, compared with $20,000 for care provided in a group home.[6]

New technologies, regulatory changes, and trends such as consumers' desire to achieve better health outcomes and take more control of their health are the major forces spurring simplified diagnostic and monitoring tools. Additional influences are skyrocketing health care costs and the greater share that patients are paying out of pocket, reduced access to care for some populations, and an increase in chronic diseases. Indeed, many of the latest technologies focus on chronic disease care, as chronic conditions require frequent monitoring and treatment and represent a large potential market for manufacturers.

Point-of-Care Tests

A small point-of-care device from Claros Diagnostics may change the way blood samples are tested for signs of infectious and immune diseases, cancer, and other ailments.

Typically, antibody tests require qualified clinical staff to draw a substantial quantity of blood for analysis by highly trained lab technicians. The enzyme-linked immunosorbent assay is a complex and expensive analysis that may take days to complete.

The Claros testing system, similar in size and design to a glucose meter, is easier, faster, and less expensive. Its credit card-size disposable cassette is preloaded with reagents that can detect multiple disease markers. In minutes, the lab-on-a-chip configuration and rapid-strip tests produce high-performance results in the doctor's office based on a finger-stick blood sample.

Quidel was a pioneer in the point-of-care diagnostics market when the company began selling dipstick pregnancy tests in 1984. Its products for health care providers, which now include tests for infectious vaginitis, chlamydia, influenza, and other medical conditions, can be administered by technicians rather than higher-skilled professionals.

Improved materials and chemical technologies have made these and many other point-of-care tests possible. New packaging for specimens enable faster testing and more accurate results. Free online training for clinical professionals is driving the use of these tests.

III. The Shift in Diagnosis, Monitoring, and Treatment Technologies

Some diagnostic devices require physician or laboratory use, but the results could be especially informative for consumers and create new decisionmaking roles for them.

AMONG THE NEW TECHNOLOGIES THAT MAKE IT POSSIBLE for mid-level clinicians and consumers to diagnose, monitor, and treat health conditions in nontraditional settings are accurate and inexpensive devices, algorithms to guide evidence-based medicine, and online capabilities.

Devices

Many diagnostic and monitoring devices now used inside and outside of clinical settings were not feasible until advances in the underlying technology made them cheaper, smaller, and less prone to incorrect use or misinterpretation of results. Such advances include simplified digital read-outs indicating if a test result is above or below normal values. These devices enable faster, more accurate, and more detailed assessments of body fluid than in the past, when a physician or highly trained nurse had to administer a blood, urine, or other fluid test, send the specimen to a lab, and interpret the results.

In addition, microchips and better information processing enable fairly sophisticated computational features to be packed into small, portable packages. An example is a device for assessing the degree of blood coagulation, or prothrombin time-international normalized ratio (PT-INR), in patients who are taking oral anticoagulants. (See box on page 6.) Ten years ago, the PT-INR instrument was a large, fixed part of laboratory equipment and cost tens of thousands of dollars. The battery-powered version now available for home use measures 3-by-4 inches, weighs less than 2 pounds, and, thanks to falling design, material, and assembly costs, retails for about $400, according to online price listings.

The most common home tests assess cholesterol, blood glucose, coagulation, fertility, and DNA; detect the presence of alcohol, tobacco, and other substances; and look for signs of urinary tract infection and infectious diseases such as hepatitis, HIV, and tuberculosis. Cholesterol testing illustrates how advances in technology and manufacturing have completely altered the testing process and greatly reduced the associated cost. Ten years ago, a simple cholesterol check required that a doctor draw a blood sample

INR Instruments

People who take anticoagulants—drugs that prevent abnormal blood clotting—for heart valve replacements, irregular heartbeat, and dangerous blood clots in the legs and lungs share a common goal: keeping blood coagulation levels within a therapeutic range.

Like diabetics who monitor their blood sugar levels, people on anticoagulants must closely monitor INR, a number that indicates how fast their blood is clotting and how well their medication is working. But unlike diabetics, most anticoagulant patients in the United States do not monitor INR at home.

The technology for in-home INR monitoring is widely available in Europe, where research shows that patients are more likely to stay within their therapeutic range if they regularly test themselves.[7–9] In contrast, a recent survey of U.S. anticoagulation clinics found that fewer than 1 percent of the patients they treat do self-testing.[10]

The main reasons for this, according to the survey's principal investigator, are the relatively high cost of the device and the fact that most insurers do not cover it. Nor do insurers reimburse anticoagulation clinics for telephone counseling when self-testers call them to report INR results.

Nearly 60 percent of clinics in the survey said their policies prohibit INR self-testing. However, most said they would consider changing such policies if patients were reimbursed for the devices and replacement cartridges.[11]

and send it to a lab for analysis. Five years ago, several manufacturers introduced cholesterol screening devices that generated results in the doctor's office and cost about $5,000, plus $50 per test. Two years ago, these respective costs had fallen to $1,200 and $20, and are now $400 and $10.[12]

Patients can have their provider perform a cholesterol test, which entails an average copayment of $28 and a total cost to the insurer of about $90. Or they can buy a non-prescription, reliable, easy-to-use test kit at the drugstore or online for around $10 (plus tax and shipping charges) and self-administer it at home. Results are available in 15 minutes. Sales of the test kits are small—in the low millions of dollars, according to retailers—but the market is growing 30 to 40 percent annually.[13]

Meanwhile, home tests are emerging for sleep apnea, colorectal cancer, Alzheimer's, influenza, strep A, and health hazards such as lead, radon, mold, asbestos, and carbon monoxide.[14]

Also on the rise are monitoring devices to ensure compliance with drug regimens and care plans. They may remind patients to take their medications, then record compliance. Several mobile phone applications enable patients to track personal factors that could affect their health, such as blood glucose level, exercise, food intake, and body functions.

Some simple devices require that a clinician be part of the care delivery or treatment decision. For example, tests for urinary tract infection can be self-administered, but a positive result means the individual must obtain a prescription to treat the condition. More complex technologies, such as home dialysis (see box on page 7), are coupled with health professional treatment.

Other technologies combine consumer and clinician input. Intel's Health Guide, for example, consists of an in-home patient device and an online interface that clinicians use to monitor and manage care remotely. Health Guide collects readings from wired and wireless tools, such as blood pressure monitors and glucose meters. Then it displays the data for the patient on a touch screen and sends the information to a health care professional.

"With more people living with chronic disease, we believe care can be increasingly moved outside of the hospital to the home," said Louis Burns, vice president and general manager of Intel's Digital Health Group. "Through our research, we've learned that a home-based model of care becomes more than

Home Dialysis

Kidney disease patients have undergone hemodialysis for decades. Three times a week in a clinic, they spend three or four hours hooked up to a machine that filters harmful wastes, extra salt, and water toxins out of their blood.

But this regimen is far from ideal because patients' health ebbs and flows with each treatment as their bodies adjust to the build-up and removal of toxins. Treatments are also extremely inconvenient—patients must organize their lives around them. Few can work while undergoing this regimen.

In-home, self-administered dialysis is more beneficial and less expensive for some patients.[15] They can sleep during the procedure; continuous treatments at home, unlike periodic treatments in a clinic, enable the body to maintain a more normal, healthy balance of fluids and chemicals; and patients can maintain a daily schedule that is closer to normal. They still receive regular medical care, including in-home professional visits.[16]

However, few kidney disease patients treat themselves at home.[17] One reason may be health care providers' heavy investment in expensive hemodialysis equipment; there is no incentive for them to encourage self-treatment.

just delivering care to patients at home—it is about creating connections to family, friends, clinicians, and the care team."[18]

Other examples include applications from BeWell Mobile and Health Hero Network. BeWell Mobile has developed mobile phone applications that enable asthmatics or diabetics and their doctors to collect and monitor the patient's data at any time and location so they can assess progress and determine if intervention is necessary. Health Hero Network's Health Buddy, a small electronic communication appliance, links patients at home with their health care providers for the purpose of monitoring chronic illnesses. It also facilitates patient education.

Some diagnostic devices require physician or laboratory use, but the results could be especially informative for consumers and create new decisionmaking roles for them. Based on testing of a saliva specimen, for example, they can learn their genetic make-up and predisposition to various conditions, such as breast cancer, that might affect their health care needs and choices.

Changes in who provides care and where it is delivered are occurring in other settings as well. For instance, nurses or technicians can now treat congestive heart failure in a clinic or outpatient setting using ultrafiltration technology, which once required a physician's supervision in the hospital, usually in the intensive care unit.

Algorithms

Another innovation fostering the shift in technologies is algorithms for evidence-based medicine. These algorithms are sets of standards, protocols, and treatment guidelines that, when combined with patient data, can produce a reliable diagnosis or treatment recommendation. They are especially helpful when, for example, nurse practitioners at retail clinics or on nurse advice lines conduct early triage or diagnosis of common conditions.

Mental health care providers, particularly clinicians and academic medical centers, have created online tests to screen for depression, addiction, obsessive-compulsive disorder, and other common psychiatric conditions. The tests do not replace a physician exam; rather, they are used to initially screen patients or direct them to an appropriate type of care. Some online programs assess individuals and then recommend actions they can take to alleviate the problem. For example, the Midwest Center for Stress and Anxiety (www.stresscenter.com/mwc) provides an online test, audio programs, and coaching for anxiety and depression.

Algorithms in Kiosks for Urinary Tract Infections

Some urgent care centers use stand-alone, algorithm-driven kiosks for fast and reliable preliminary diagnoses of patients who may have an uncomplicated urinary tract infection. Such infections account for about 8 million medical visits annually, 1 in 10 of which are managed in emergency departments.[19]

Women who present with typical symptoms answer 20 to 30 simple questions on the kiosk. If their answers indicate they qualify for computer-directed treatment, a clinician receives a printout with the patient's information, including her medical history, symptoms, current medications, and medication allergies.

A nurse or physician reviews the printout, selects an appropriate antibiotic, and signs the prescription. The patient receives the printout, and a copy is placed in her medical record.

This approach demonstrates that computer-assisted diagnosis can be clinically effective, improve access to care, and reduce costs and inefficiencies. Providers are now using kiosks and evidence-based algorithms for chlamydia, vaginitis, emergency contraception, and birth control.[20–22]

Some radiologists use computer-aided detection (CAD), which relies on algorithms, to confirm the presence of breast cancer after an initial mammogram reading. One of every 200 films shows a suspicious pattern.[23] In such cases, CAD helps radiologists identify cancerous patterns in a mammogram by tapping a database of cancer images. One-third of all second mammogram readings are now done by CAD.[24]

Online Search, Information, and Interconnectivity

Web technologies are making it easier for consumers to find information about new treatments and to try new medical products or learn how to use them at home, perhaps by viewing an Internet video with a step-by-step explanation. How-to sites and demonstrations are among the most popular online destinations, with eHow, Expert Village, Instructables, SuTree, WonderHowTo, Howcast, and others offering hundreds of thousands of videos on every conceivable subject.[25] eHow alone claims to have more than 26 million unique visitors per month,[26] and a search for "glucose test" on YouTube yields dozens of user-generated videos. At some Web sites, device manufacturers, health experts, and patients explain simple medical procedures via text, photos, video, or audio.

It is difficult to definitively determine the total number of Web pages, but Cuil, a new search engine and Google rival, provides access to more than 124 billion.[27] During the first quarter of 2007, health information Web sites received an average

Table 1. Most Popular Health Web Sites

	UNIQUE MONTHLY VISITORS* (millions)
www.webmd.com	14.8
www.nih.gov	8.1
www.everydayhealth.com	6.1
www.mayoclinic.com	5.8
www.medicinenet.com	4.6
www.revolutionhealth.com	3.4
www.drugs.com	3.3
www.healthline.com	3.0
www.medhelp.org	2.0
www.rxlist.com	1.7

Sources: *Compete.com, †Alexa.com

of 55.3 million visitors per month—31 percent of the total U.S. Internet audience and an increase of 12 percent from the same quarter in 2006.[28] According to Alexa.com, a Web traffic information and search service, there are more than 62,000 health sites. Search technology continues to advance, enabling consumers to quickly find precisely what they want.

Coupled with information, online interactivity—sometimes with a health care professional or other patients—enables better monitoring of conditions or a treatment program than traditional doctor visits, which may occur less frequently and require a greater investment of money and time. At social networking sites such as DailyStrength (www.dailystrength.org) and Diabetes Mine (www.diabetesmine.com), patients can access tools to monitor their conditions and connect with other patients more conveniently than in face-to-face support groups.

Social Networking Sites

The number of Americans who visit social networking Web sites is increasing. During June 2008, nearly 190 million visited at least one such site—a 6 percent increase from June 2007—and spent an average of 1,650 minutes doing so.[29]

In addition to especially popular destinations, such as Facebook (www.facebook.com) and MySpace.com, there are social networking sites that focus on health or other specific interests. Their number and popularity also are increasing.[30] They include the information-sharing and support sites PatientsLikeMe (www.patientslikeme.com) and MDJunction.com, which connect patients who have similar diagnoses.

Similarly, at sites such as Traineo (www.traineo.com) and MyNetDiary (www.mynetdiary.com), visitors can track their fitness progress and weight loss, as well as interact with others.

IV. Government Regulation

Even if the FDA has approved a medical test for use outside the laboratory, some states limit consumers' access to them.

Federal Oversight

The U.S. Food and Drug Administration (FDA) oversees medical devices as well as medications, granting market approval to those it deems safe and effective. The FDA's very broad definition of "medical device" encompasses everything from tongue depressors to artificial hearts, medical software, and algorithms. (See Appendix A for a brief history of medical device regulation.)

To be marketed successfully, new point-of-care tests need a waiver from FDA review under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Waived tests, such as those for pregnancy or strep throat, are so simple and accurate that the likelihood of erroneous results is negligible and, if errors do occur, there is little risk of harm.

As of August 2008, the FDA had granted more than 3,000 CLIA waivers for medical devices.[31] Many of these were designed for point-of-care use in doctor offices or clinics rather than labs. Congress revised the CLIA waiver provisions in 1997 to clarify that tests the FDA approved for home use would automatically qualify for a CLIA waiver, which can dramatically shorten the time it takes for them to enter the market.

A combination of more CLIA waivers, less restrictive regulations, clearer design guidelines, standards for exemptions, and an OTC-friendly FDA will likely result in more devices becoming available to mid-level clinicians and consumers in coming years.

State Oversight

Some states have medical device regulations that supplement and may differ from federal requirements. In California, the Sherman Food, Drug, and Cosmetic Law of 1970 authorized the state to license and inspect device manufacturers before they can make and distribute their products. Manufacturers must demonstrate satisfactory compliance with the federal Good Manufacturing Practices/Quality System regulation. Investigators in the state's Food and Drug Branch have broad authority to inspect and remove noncompliant devices from the market. Amendments to the Sherman Law in the

1999–2000 legislative session established a licensing program for home medical device retailers.[32]

Even if the FDA has approved a medical test for use outside the laboratory, some states limit consumers' access to them. One major restriction is tests that only physicians may order. Another specifies whether consumers may receive test results directly from the lab or the results must be sent to a doctor.

Any Lab Test, a national franchise that offers consumers a wide range of blood and urine tests in convenient locations, illustrates how state limitations vary. Its "draw centers" take samples and send them to a certified lab for analysis. In some states, notably Florida, anyone may walk into a draw center and order a paternity, drug, or other type of test and receive the results by mail, phone, or fax the next day. In other states, only a physician may order certain tests and receive the results.

In 2008, the California Department of Public Health ordered 13 genetic testing companies, including 23andMe, deCODEme, SeqWright, and Navigenics, to stop selling their services directly to state residents. It claimed that under the Sherman Act, the companies must be licensed and that physicians, rather than consumers, must order genetic tests.[33]

V. Consumer Trends

Few researchers have studied how consumers make decisions and trade-offs regarding where they receive health care, be it in a doctor's office, an express clinic, or at home.

To be viable, the new technologies described in this report require consumer demand. Outside of the doctor's office, patients must be aware of the clinic-based or self-care option, be comfortable with it, and be willing to try it and pay the related cost. Trends that are fostering this market include a strong consumer interest in taking personal control of health, concerns about privacy, and more targeted marketing by both manufacturers and a growing number of distribution channels.[34]

Patient Empowerment

In the last decade, there have been significant shifts in consumer perspectives on health, health care providers, and alternative therapies, including self-directed treatments. Simply put, many patients who once deferred to physicians have become active health care shoppers on their own behalf. They now have the information, interest, and financial incentive to consume health care products and services more like they consume other merchandise and services. In addition, social norms have shifted, allowing more public discussion of even sensitive health issues.

Consumer Reports highlights this empowerment. The monthly magazine, which has a well-staffed health editorial group, reviews medical devices, health insurance, and medications along with many other products. The September 2008 issue, for example, focused on OTC and prescription blood pressure monitors, blood glucose monitors, and sleep aids.

"Consumers…want information they can take action on—whether to see a health care professional [for a] a screening test, purchase a home device, or take certain medications," a *Consumer Reports* spokesperson said. "Very few…have an esoteric interest in simply knowing more about their overall health. This might change with new genetic information, but we don't think so."[35]

Few researchers have studied how consumers make decisions and trade-offs regarding where they receive health care, be it in a doctor's office, an express clinic, or at home. Nor have many researchers examined the purchasing process and the criteria consumers use to

evaluate lower-acuity health care settings or self-care devices. If companies gather information about these and other considerations, there is little incentive for them to release it publicly. Among many unanswered questions are whether demographic factors such as age, income, or gender, or perhaps insurance status or overall health, affect consumers' purchasing decisions.

Concerns about Privacy

Consumers' desire for health care privacy is also driving the greater use of clinic- or home-based diagnostic and monitoring devices. OTC pregnancy, fertility, ovulation, and other tests have proved to be highly popular in part because they offer privacy.

Teens say that privacy and confidentiality are important factors in their willingness to undergo tests for sexually transmitted diseases. If they could self-test and thereby avoid the family physician, it might alleviate their privacy concerns and increase the testing rate.[36] Several studies have suggested that teens forego regular health care and screenings due to confidentiality concerns.[37]

Worries about denial of insurance coverage or employment discrimination are other reasons consumers seek privacy, especially in the age of genetic testing. However, enactment of the federal Genetic Information Nondiscrimination Act (GINA) of 2008 will likely boost the genetic-test market.[38] GINA, which protects the privacy of personal genetic information and outlaws related discrimination by health insurers and employers, seeks to instill confidence in consumers and practitioners so they will take greater advantage of predictive tests.

Targeted Marketing and More Distribution Channels

Two marketing trends driving adoption of self-care technologies are manufacturers' ability to reach and serve niche consumer markets profitably, and the growing number of distribution channels and sales outlets for products and services.

In the past, device manufacturers targeted only very large markets — those comprising at least 2 million consumers, such as patients with diabetes or pregnant women — given the expense of mass marketing. Many technically feasible devices have not been commercialized for this reason alone. Now, however, companies can more easily and profitably tap specific consumer markets, thanks to highly targeted marketing strategies and diverse distribution channels. These include targeted print media, direct-marketing customer lists, specialty cable TV channels, and online marketing via banner ads, sponsored searches, email campaigns, and the like.

For example, the genetic testing company 23andMe targets adoptees, people who are planning to have children, and parents with newborns. Anne Wojcicki, the company's founder and vice president, said 23andMe tailors ad campaigns to each of these "very tiny markets with specific needs" and keeps a lid on costs by purchasing space in specific media and by marketing online.

A plethora of sales outlets also abets self-care technologies. In the past, doctors prescribed medical devices, patients retrieved them at pharmacies, and insurers covered most or all of the cost. Although pharmacies clearly have a lead as outlets for prescription and OTC devices and medications, other retailers — grocery chains, mass merchandisers such as Wal-Mart and Target, warehouse stores such as Costco and BJ's Wholesale Club, Internet outlets such as Amazon.com, and catalog retailers and department stores — are emerging as strong

competitors. The convergence of consumer electronics and health technology will probably strengthen as marketers find ways to capitalize on shoppers' appetite for health-related products.

Retailers are tapping into this consumer demand. Drug stores report they are allocating more shelf space to home diagnostic and monitoring products, more square feet to clinics, and more space for pharmacy consultations.[39] Electronics retailers have increased their space for health-care or related devices such as pedometers, blood-pressure and glucose monitors, and reminder technologies.[40] A product subcategory at Amazon.com offers more than 100 diagnostic tests and medical devices. The home medical category at Wal-Mart.com lists more than 500 products—everything from home testing devices to diabetes management and mobility aids, blood pressure monitors, walkers, and bed rails. Online outlets at Costco, CVS, Walgreens, and other merchandisers carry similar products.

At the Consumer Electronics Show in 2008, manufacturers showcased a variety of new gadgets, including devices for delivering medication and for managing macular degeneration, OTC hearing aids for mild hearing loss, personal electronic health records, and smart pillboxes. A device that won an award enables remote caregivers or health care providers to visually monitor seniors or people with disabilities in the home setting.

VI. Implications

Research suggests that some types of medical devices for home use improve health outcomes. However, the overall findings, while mainly positive, have been mixed.

At first glance, the shift in diagnosis, monitoring, and treatment technologies appears to be a positive development. Mid-level clinicians can administer tests that once were the exclusive purview of physicians and laboratories, which makes diagnostic, monitoring, and treatment capabilities more widely accessible. Patients are taking more control of their health and wellness, and they have better, more convenient, and less expensive technologies at their disposal.

But this trend also raises important issues regarding health outcomes, device safety and design, cost and reimbursement, and the response of mainstream health care.

Health Outcomes

Research suggests that some types of medical devices for home use improve health outcomes. However, the overall findings, while mainly positive, have been mixed.

According to several clinical studies in 2001, remote computer monitoring of blood glucose levels in diabetics at home improved their outcomes.[41] Other research found that asthma patients who had never used a computer learned how to test their lung function at home with a breathing device and Internet-based monitoring system. The results of this approach were comparable to testing performed by a medical professional.[42]

Research on home monitoring of anticoagulation therapy also showed improved outcomes. Patients were more likely to stay within recommended therapeutic ranges if they regularly monitored coagulation. Point-of-care testing in elderly patients led to tighter control and a lower incidence of major hemorrhage, especially at the beginning of anticoagulant treatment. Larger prospective, randomized intervention studies demonstrated that patients who managed anticoagulation therapy themselves spent more time within the target range.[43]

But home devices for patients do not always result in better outcomes. An example is remotely monitored high-risk pregnancies. Managing the technological applications for this purpose has proved

difficult in the home environment, illustrating the need for further research and regulatory controls.

Safety and Design

Some experts have raised concerns about whether consumers use home devices safely and appropriately. Noting that "[t]here are just too many opportunities to make bad mistakes," Stephen B. Kaufman, a pioneer researcher in home-care technology, said he supports device technology that has "simple prompts" and eliminates the "possibility of mistakes."[44] To reduce the likelihood of error, the FDA's Center for Devices and Radiological Health has provided human factors guidance to manufacturers on device design.[45]

Several studies have looked at appropriate use of certain home devices. For example, researchers found that women could learn from packaging information how to use an OTC vaginal pH self-test and administer it as accurately as physicians. In addition, the researchers concluded that the self-test may be a convenient tool to help women determine whether they should use an OTC antifungal medication or go to a physician for a full diagnostic work-up.[46]

Researchers are also assessing consumers' ability to administer and interpret complex tests effectively. Investigators who studied the use of a self-administered kit for fecal occult blood testing among a Chinese population in Taiwan found that while the technology was easy to use, participants had difficulty interpreting the results.[47]

Another question is whether some tests — such as the blood test for prostate-specific antigen, which often is elevated in men who have prostate cancer — produce high rates of false-positive results, which could lead to unnecessary further testing and biopsies.

Adverse events associated with medical devices are an under-recognized public health problem, one study concluded. It found that 42 percent of medical-device injuries that prompted a visit to the emergency department occurred at home. It was unclear in these cases if the devices had been approved for home use, were misused or used off-label, resulted in an accident despite proper use, or came with poor instructions.[48]

Unlike diagnostic and monitoring devices for clinical settings, those for the home must be designed to accommodate a broader array of environments and more diverse users. The FDA offers design guidance in the Good Manufacturing Practice/Quality Systems regulation, but there are no formal standards for manufacturers to meet when they create new technologies or prepare instructions on how to use them.

Typically, the design of commercial products differs from that of consumer products, which must be rugged and easy to learn and use. For example, the controls on a device and related instructions need to be tailored in such a way that the targeted users — seniors, children, people who do not speak English, or other populations — can understand them.[49] Designers also focus on a product's affinity, or emotional appeal, so consumers will more likely accept and use it properly and continuously. Oftentimes, an in-home device — such as infrared ear thermometers, which produce a digital read-out and are now widely available for retail purchase — is more acceptable if in the past it was only available to clinicians.[50]

Among the more innovative recent devices are injection needles with safety shields to prevent accidental sticks; a flat-screen, easy-to-read blood pressure monitor and clock that sits on a horizontal surface for convenient access; a continence care kit; a subcutaneous injection device that administers pre-set doses of growth hormone to children; and a forehead thermometer.[51]

Cost and Reimbursement

The shift in diagnosis, monitoring, and treatment to mid-level clinicians and consumers can obscure the cost and reimbursement picture. Insurers generally reimburse physician offices and clinics for the cost of tests administered by mid-level practitioners, but many payers are slow to change their reimbursement policies, due partly to concerns about duplicate tests or procedures. Email exchanges between doctors and patients are just beginning to be reimbursed, but telephone counseling—after a patient transmits monitoring data from home, for example—typically is not. And if a consumer's copayment is low, it may be cheaper for her to undergo a test at the doctor's office even though the in-office test, in absolute terms, is more expensive than one for home use.

Health care costs greatly influence technology adoption. In earlier decades, new technologies were attractive to consumers partly because insurers paid most or all of the expense; there was little financial incentive to opt for clinic or home care. Now, as consumers bear an ever-larger share of those costs, they may be less inclined to pay out of pocket for more expensive technologies or take other action to address a medical concern. Indeed, in one survey, more than a third of consumers with high-deductible insurance coverage reported that they avoided or delayed medical care because of cost, compared to 17 percent of those with comprehensive coverage. More than a quarter of those with high-deductible policies said they skimped on prescription drugs because of cost, compared to 16 percent of respondents with comprehensive policies.[52]

On the other hand, as copayments and total deductibles continue to rise,[53] the lower cost and greater convenience of certain types of clinic or self-care are likely to become more attractive alternatives for consumers.

Seniors and their caregivers are willing to try home-based technologies, such as sensors that detect falls, according to a 2008 study commissioned by the AARP Foundation. However, the study also found that cost was a barrier: 80 percent of respondents at least 65 years old and 75 percent of caregivers indicated they were willing to pay only $50 per month or less for fall-monitoring service.[54]

In coming years, Best Buy, Radio Shack, and other large, price-conscious electronics retailers may dedicate more shelf space to high-margin OTC devices. In-home defibrillators retail for up to $1,000 and various types of monitors for $50 to $200 or more.[55]

Resistance from Mainstream Providers

Apparently, few physicians recommend home or clinic testing of common ailments. There is minimal or no incentive for them to do so, in contrast to in-office testing that generates revenue and enables face-to-face contact with patients. Consumers, on the other hand, may benefit from the lower cost and greater convenience of clinic-based or home testing. For example, home tests for yeast infection or urinary tract infection cost only about $15 and are available at most drug stores. A test performed at the doctor's office costs much more, possibly includes a copayment, and entails scheduling an appointment and traveling to and from the office.

New technologies entering the market challenge the role and purview of physicians and other health care professionals. Similar issues arose when retail clinics came into being. While some clinicians embrace home devices and encourage patients to bring them and the data they collect to office visits so health professionals can deliver enhanced care, others resist recommending or prescribing such devices. Several professional audiologist associations oppose shifting from prescription to OTC hearing aids for

serious hearing loss (see box), arguing that testing by a professional is necessary for quality control and to ensure correct adjustment of the devices.

Health professionals with an exclusive right to conduct tests may lobby legislatures to legally prevent testing by mid-level clinicians or consumers, even if a technology is simple and safe. For example, the American Medical Association issued recommendations in June 2008 opposing direct-to-consumer genetic testing.[56,57]

OTC Hearing Aids

In the not-too-distant future, OTC hearing aids for serious hearing loss may become available.

Currently, before audiologists prescribe a hearing aid, they test patients by administering several sounds of different volumes, tones, and frequencies. Patients confirm whether or not they can hear a sound and distinguish between distinct sounds.

Several companies are considering automating this test. The consumer would self-test in a quiet room with a computer terminal and receive the results directly or have a technician administer the test and verify the results. Then, the computer would appropriately program the hearing aid and teach the patient how to insert and use it.

OTC sales of this technology could make hearing aids more available to people with low incomes.

VII. Conclusion and Key Questions

A better understanding of how consumers decide to use which particular tools, how the tools improve or hinder access to health care, and how they affect health outcomes will be vital.

THE SHIFT OF NUMEROUS DIAGNOSTIC, monitoring, and treatment technologies from physicians to mid-level clinicians and consumers could significantly increase the health care system's capacity, improve access to and the quality of care, and reduce costs. However, if the shift continues, a better understanding of how consumers decide to use which particular tools, how the tools improve or hinder access to health care, and how they affect health outcomes will be vital. Comprehensive research and health payment reform are necessary to foster and direct this market, and some additional government regulation may be necessary.

The trend raises a number of key questions for further discussion and research:

- ***Is the use of new diagnosis and monitoring technologies by mid-level clinicians and consumers safe, effective, and appropriate?*** Research on this important issue has been minimal. Some studies have looked at whether specific technologies are used correctly. Others suggest that certain devices improve health outcomes. But evidence regarding safety, effectiveness, and appropriate use is mixed. It is still unclear, for example, which factors—consumer characteristics, the medical condition or disease, the type of technology, how the technology is used, or others—lead to better outcomes.
- ***How might the contrasting perspectives of physicians and many consumers regarding new technologies and self-treatment be reconciled?*** Older physicians tend to favor in-person diagnosis and treatment, while many younger clinicians are comfortable with email communications, video consultations, and self-care. Bridging this gulf—by determining, for example, what kind of evidence would convince physicians that new technologies and self-care can be beneficial—might speed the shift to more convenient, consumer-friendly diagnosis, monitoring, and treatment technologies.

- ***How might insurers structure provider and consumer incentives, benefits, and education to foster this shift?*** Physicians do not typically recommend clinic or self-testing of common ailments. There are few if any incentives for them to do so. As heightened interest in cost control in the health care system meets an increasingly engaged consumer, payers may begin creating new business models and structures to facilitate the shift.

- ***What legal issues need to be resolved for these technologies to gain momentum?*** Who is ultimately responsible for the safe use of self-care technologies — manufacturers, health care providers, consumers, or companies that electronically transmit data from consumers to clinicians? Legal liability issues in this area present challenges for the regulatory system. The problem is especially complex given the many different types of technologies entering the market, and more guidance from the FDA and Congress will likely be necessary.

Appendix A: A Brief History of Medical Device Regulation

Federal oversight of medical products, including devices, began with the Food, Drug, and Cosmetic Act of 1938. Initially, the law's objective was to weed out unsafe products that were already available. Amendments in 1976 gave the FDA authority to determine the safety and effectiveness of devices before they went to market. The Agency categorizes devices as Class I, II, or III, which signify increasing levels of comparative risk and dictate the degree of regulatory scrutiny.

A rapid proliferation of medical technologies in the late 1980s and early '90s severely stressed the regulatory system, causing major delays in product clearance. In 1980, a new drug or device might typically undergo 30 clinical trials involving about 1,500 patients before it received FDA approval. Those numbers had reached more than 60 clinical trials and about 5,000 patients by the mid-1990s.[58]

Pressure to reform the approval process led to passage of the Food and Drug Administration Modernization Act of 1997, which made medical device reviews more efficient. For example, an accredited third party can now review devices that manufacturers claim are "substantially equivalent" to commercially available devices, reporting and testing requirements are less rigorous, and manufacturers need not disseminate as much product information as previously. Some researchers maintain that current reporting and testing standards are lower than those for pharmaceuticals.[59]

The Medical Device User Fee and Modernization Act of 2002 mandated that the FDA not only ascertain the safety of devices, but also move the devices it approves to market in a timely manner. The law contains performance goals and review criteria to foster more efficient processing of applications. The Food and Drug Administration Amendments Act of 2007 allocated more resources to the FDA so it could process approval applications more quickly.

Two devices now widely available for home and other use—automated external defibrillators to restore normal heart rhythm after cardiac arrest and a pad that helps women detect lumps during breast self-examination—illustrate what can nevertheless be a long and complex FDA approval process.

It took seven years before the first OTC defibrillator received approval in 2004. Although Philips, the manufacturer of HeartStart, rightly had to demonstrate that consumers could safely and effectively use its product, FDA requests for information over the years were frequent, sporadic, uncoordinated, and often unclear. Today, dozens of different types and brands of automated external defibrillators are on the retail market. Many units are available in public places.

Nearly a decade passed before Inventive Products received FDA approval for a prescription version of the Sensor Pad it had invented in 1986. The simple lump-detection aid consists of silicon lubricant sandwiched between two plastic sheets. Initially, the FDA classified the pad as a high-risk device because there was no other substantially equivalent product on the market. It also requested proof, in addition to effectiveness data, that the pad reduced breast cancer mortality. This would have entailed clinical trials involving thousands of women over many years.

To circumvent these regulatory hurdles, Inventive Products sold the Sensor Pad to hospitals, which in turn gave them to women for home use. In response, the FDA confiscated the pads in 1989, and lawsuits and congressional hearings followed. In 1995, the agency approved Sensor Pad for prescription use only and, in 1996, for OTC use. Today, several brands are available at retail outlets and gyms, as well as online, for $25.

Appendix B: CLIA Regulations

To be marketed successfully, new point-of-care tests need a waiver under the Clinical Laboratory Improvement Amendments of 1988. Waived tests, such as those for pregnancy or strep throat, are so simple and accurate that the likelihood of erroneous results is negligible and, if errors do occur, there is no reasonable risk of harm. These tests yield quick results and are not intended to compete with other more complex tests performed in laboratories.

Categories of tests that qualify for a CLIA waiver include:

- Dipstick or tablet reagent urinalysis (non-automated) for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen;
- Fecal occult blood;
- Ovulation (visual color comparison for luteinizing hormone);
- Pregnancy (visual color comparison in urine);
- Erythrocyte sedimentation rate (non-automated);
- Hemoglobin-copper sulfate (non-automated);
- Hemoglobin by single-analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and read-out;
- Blood glucose by FDA-approved monitoring devices specifically for home use; and
- Spun microhematocrit.

Congress revised CLIA in 1997 such that tests approved by the FDA automatically qualified for a waiver. Although the revisions did not include home-use tests designed specifically for medical professionals, these versions would undergo an expedited waiver review; regulators only needed to determine if differences between the consumer and professional versions warranted a waiver for the latter.

Endnotes

1. "Fact Sheet: The Use of Over-the-Counter Medicines." Be MedWise: September 2003 (www.bemedwise.org/press_room/sep_2003_fact_otc.pdf).
2. "Global point-of-care testing market forecasted to grow to over $18.7 billion by 2011." AllBusiness: October 4, 2007 (www.allbusiness.com/medicine-health/diagnostics-screening/5285485-1.html).
3. "Home blood-pressure monitor market to reach $1bn by 2010." MTB Europe: January 30, 2007 (www.mtbeurope.info/news/2007/701030.htm).
4. *Worldwide Markets and Emerging Technologies for Point-of-Care Testing.* Life Science Intelligence: 2006.
5. *U.S. Market for Home Healthcare Products.* Life Science Intelligence: 2009.
6. Keehan, S., Sisko, A., Truffer, C., and others. "Health spending projections through 2017: The baby-boom generation is coming to Medicare." *Health Affairs* 2008;27(2): w145–w155.
7. Hambleton, J. "Home monitoring of anticoagulation." *Journal of Thrombosis and Thrombolysis* 2003;16(1–2): 39–42.
8. Heneghan, C., Alonso-Coello, P., Garcia-Alamino, J.M., and others. "Self-monitoring of oral coagulation: A systematic review and meta-analysis." *Lancet* 2006;367(9508): 404–411.
9. Gardiner, C., Williams, K., Longair, I., and others. "A randomised control trial of patient self-management of oral anticoagulation compared with patient self-testing." *British Journal of Haematology* 2006;132(5): 598–603.
10. Wittkowsky, A.K., Sekreta, C.M., Nutescu, E.A., and others. "Barriers to patient self-testing of prothrombin time: National survey of anticoagulation practitioners." *Pharmacotherapy* 2005;25(2): 265–269.
11. Ham, B. "Self-test: Are patients ready?" *Center for Advancing Health, Facts of Life* 2006;11(9).
12. This information comes from Cholestech (www.cholestech.com/products/index.htm).
13. This information is based on confidential discussions with CVS, Walgreens, and Wal-Mart representatives in 2008.
14. *Over-the-Counter Diagnostic Product World Markets.* TriMark Publications: September 2006.
15. Kumar, V.A., Ledezma, M.L., Idroos, M.L., and others. "Hospitalization rates in daily home hemodialysis versus peritoneal dialysis patients in the United States." *American Journal of Kidney Disease* 2008;52(4): 737–744.
16. "Renal dialysis: Night and day." *Outlook* 2002;39(2): 18 (outlook.wustl.edu/summer2002/nightandday.pdf).
17. *U.S. Hemodialysis Equipment and Services Market.* The Infoshop: October 2008.
18. "Intel receives FDA market clearance on in-home medical device for management of health conditions." Intel: July 10, 2008 (www.intel.com/pressroom/archive/releases/20080710corp_b.htm).
19. Gupta, K., Hooton, T.M., Roberts, P.L., and others. "Patient-initiated treatment of uncomplicated recurrent urinary tract infections in young women." *Annals of Internal Medicine* 2001;135(1): 9–16.
20. Ralph Gonzales, personal communication, June 2008.
21. Aagaard, E.M., Nadler, P., Adler, J., and others. "An interactive computer kiosk module for the treatment of recurrent uncomplicated cystitis in women." *Journal of General Internal Medicine* 2006;21(11): 1156–1159 (www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1831661#b3UTI).
22. DeGier, V. "Computer reduces wait for women with urinary tract infections." University of California, San Francisco: February 18, 2005 (pub.ucsf.edu/newsservices/releases/200502183).
23. Hejazi, M.R., Ho, Y-S. "Automated Detection of Tumors in Mammograms Using Two Segments for Classification," in *Advances in Multimedia Information Processing.* Berlin: Springer, 2005.
24. Ibid.

25. Heffernan, V. "Tiny talents." *New York Times Magazine:* August 15, 2008 (www.nytimes.com/2008/08/17/magazine/17wwln-medium-t.html).

26. What is eHow.com? eHow.com (www.ehow.com/about_us/about_us.aspx).

27. See www.cuil.com.

28. "Online health information category grows 12 percent in Q1 2007 versus last year to more than 55 million visitors per month." comScore: May 21, 2007 (www.comscore.com/press/release.asp?press=1440).

29. Sarasohn-Kahn, J. *The Wisdom of Patients: Health Care Meets Online Social Media.* California HealthCare Foundation: April 2008 (www.chcf.org/documents/chronicdisease/HealthCareSocialMedia.pdf).

30. Ibid.

31. Tests Waived by FDA From January 2000 to Present. U.S. Food and Drug Administration (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm).

32. Medical Device Safety Program. Department of Health Care Services, California Department of Public Health: 2007 (www.dhs.ca.gov/fdb/HTML/device/mddesc.htm).

33. "California cracks down on DTC genetic testing." Washington G2 Reports, August 2008 (www.g2reports.com/issues/DTTR/2008_8/1617382-1.html).

34. *Catch the New Pharma Marketing Wave.* Manhattan Research: November 2008.

35. Personal communication, September 2008. The spokesperson preferred not to be quoted by name.

36. Blake, D.R., Kearney, M.H., Oakes, J.M., and others. "Improving participation in Chlamydia screening programs: Perspectives of high-risk youth." *Archives of Pediatric & Adolescent Medicine* 2003;157(6): 523–529.

37. Leatherman, S., McCarthy, D. *Quality of Health Care for Children and Adolescents: A Chartbook.* The Commonwealth Fund: April 2004 (www.commonwealthfund.org/~/media/Files/Publications/Chartbook/2004/Apr/Quality%20of%20Care%20for%20Children%20and%20Adolescents%20%20A%20Chartbook/leatherman_pedchartbook_700%20pdf.pdf).

38. Terry, M. (ed). *Laboratory Market Leaders Report 2008.* Washington G-2 Reports: 2007.

39. This information is based on confidential discussions with CVS, Walgreens, and Wal-Mart representatives in 2008.

40. *Next Generation Health Care Providers—I Didn't Know You Cared.* Research and Markets: October 2003.

41. Lewis, C. "Emerging trends in medical device technology: Home is where the heart monitor is." *FDA Consumer:* May/June 2001 (www.fda.gov/Fdac/features/2001/301_home.html).

42. Finkelstein, J., Cabrera, M.R., Hripcsak, G. "Internet based home asthma telemonitoring: Can patients handle the technology?" *Chest* 2000;117(1): 148–155.

43. See note 7.

44. See note 42.

45. See *Guidance for Industry and FDA Premarket and Design Control Reviewers. Medical Device Use-Safety: Incorporating Human Factors Engineering Into Risk Management.* U.S. Food and Drug Administration: July 18, 2000 (www.fda.gov/cdrh/humfac/1497.html).

46. Roy, S., Caillouette, J.C., Faden, J.S., and others. "The role of an over-the-counter vaginal pH self-test device package insert: Can subjects learn what the device is for and how to use it?" *American Journal of Obstetrics and Gynecology* 2005; 192(6): 1963–1967.

47. Hou, S.I. "Experience of colorectal cancer screening using a home-administered kit for fecal occult blood tests among a Chinese worksite population in Taiwan." *Psychological Reports* 2005;96(1): 178–180.

48. Hefflin, B.J., Gross, T.P., Schroeder, T.J. "Estimates of medical device-associated adverse events from emergency departments." *American Journal of Preventive Medicine* 2004;27(3): 246–253.

49. Jordan, M. "Considerations for home-based devices." *Medical Device & Diagnostic Industry:* February 2008 (www.devicelink.com/mddi/archive/08/02/004.html).

50. Lanseng, E.J., Andreassen, T.W. "Electronic healthcare: A study of people's readiness and attitude toward performing self-diagnosis." *International Journal of Service Industry Management* 2007;18(4): 394–417.

51. See the Medical Device Excellence Awards for 2008 and previous years at www.devicelink.com/expo/awards.

52. Fronstin, P., Collins, S.R. *Early Experience With High-Deductible and Consumer-Driven Health Plans: Findings From the EBRI/Commonwealth Fund Consumerism in Health Care Survey.* Employee Benefit Research Institute and Commonwealth Fund, Issue Brief No. 288: December 2005 (www.ebri.org/publications/ib/index.cfm?fa=ibDisp&content_id=3606).

53. The current national average for copayments is $28. Claxton, G., Gabel, J., DiJulio, B., and others. "Health benefits in 2007: Premium increases fall to an eight-year low, while offer rates and enrollment remain stable." *Health Affairs* 2007;26(5): 1407–1416.

54. "Older people want to use technology to help them remain at home." *Medical News Today:* April 2, 2008 (www.medicalnewstoday.com/articles/102494.php).

55. This information comes from interviews with buyers who work for retailers and from prices published online.

56. *Survey of Direct-to-Consumer Testing Statutes and Regulations.* Genetics & Public Policy Center: June 2007 (www.dnapolicy.org/resources/DTCStateLawChart.pdf).

57. "American Medical Association adopts new direct-to-consumer genetic testing policy recommendations." *Medical News Today:* August 14, 2008 (www.medicalnewstoday.com/articles/118231.php).

58. The Drug Development and Approval Process. Independent Review/FDAReview.org (www.fdareview.org/approval_process.shtml).

59. Feldman, M.D., Petersen, A.J., Karliner, L.S., and others. "Who is responsible for evaluating the safety and effectiveness of medical devices? The role of independent technology assessment." *Journal of General Internal Medicine* 2008;23(Suppl 1): 57–63.

California
HealthCare
Foundation

1438 Webster Street, Suite 400
Oakland, CA 94612
tel: 510.238.1040
fax: 510.238.1388
www.chcf.org