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THE JOURNAL OF LIFE SCIENCES

FALL 2009

The Future of Medicine

Solving the genetic puzzle of disease and wellness

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The Future Is Now

The potential of genetics-based personalized medicine is just coming into focus. Five years ago, Burrill & Company hosted its first Personalized Medicine Meeting. At that time, we postulated that there was a shift towards more personalized, predictable, and preventive medicine that would revolutionize the healthcare system.

Fast forward five years and we see that the new medical reality is now with us. The impact of genomics, proteomics, pharmacogenomics, and systems biology on the development of more targeted and personalized therapeutics and diagnostics is beginning to be felt. Personalized medicine is now firmly on the radar screen of governments across the globe. Drug developers have shifted their focus from the one-size-fits-all drug model, to individually tailored medicines. Drug companies are now using genetics and other screening tools to figure out what patients are best suited for their treatments. The movement is most obvious in cancer, where drugs have been approved specifically for a subpopulation of patients displaying particular genotypes.

Pharmaceutical companies now understand the contribution of biomarkers and genetics-based diagnostics. There are new alliances and collaborations being forged for the research and development of companion diagnostics and this trend will continue to expand.

Personalized medicine is being embraced by many countries from Luxembourg to Singapore. In the United Kingdom, for example, the Science and Technology Committee of the House of Lords recently issued a report on genomic medicine. The report is optimistic about the potential long-term benefits of translating advances in genetics into substantial improvements in medical care. "Every so often, a scientific advance offers new opportunities for making real advances in medical care," the report says. "From the evidence given to this inquiry, we believe that the sequencing of the human genome, and the knowledge and technological advances that accompanied this landmark achievement, represent such an advance."

As the report suggests, there has never been a more exciting time in the history of medicine than now. We are on the threshold of revolutionary changes in the healthcare landscape. It is not surprising that payors, policymakers, the pharmaceutical industry, and patients are counting on our industry to deliver on its promise of transforming medicine. The goal is to make it better able to address the ailments of an aging population, control burgeoning healthcare costs, and counter the threat of pandemics.

Already, there's been a dizzying advance of technology to enable personalized medicine. And the business case for personalized medicine has become clear. But the politics surrounding it remains less clear. We have a president who has acknowledged the value of personalized medicine. The appointment of Francis Collins as the new director of the National Institutes of Health provides a strong advocate. But as battles over healthcare reform brew, it is critical the industry works to ensure public policy helps, not hinders, the ushering in of this new era of medicine.

One concern among personalized medicine advocates centers on new funding for comparative effectiveness research that some fear could hurt the development of personalized medicine. Recently, the Partnership to Improve Patient Care, a coalition of patient, provider, and industry advocacy groups, raised concerns that comparative effectiveness research will not take adequate account of individual patient differences. The fear is it may impede the development and adoption of improvements in medical care and "stymie progress in personalized medicine."

Despite the concerns, most agree that personalized medicine will become part of the solution to what ails the U.S. healthcare system. Everyone has a stake in the success of this new era of medicine.

G. Steven Burrill

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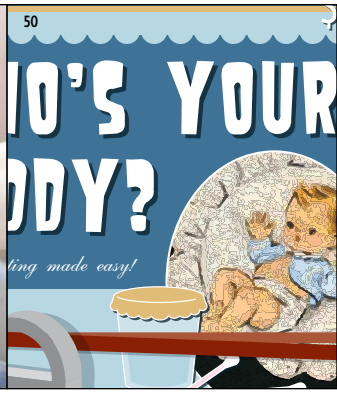

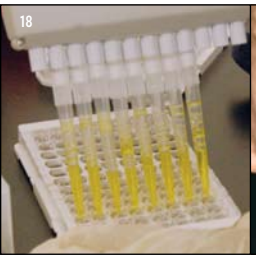

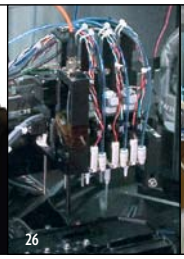

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Advisory Board

LEGISLATION

Medical Bills

Washington is taking note of the promise of personalized medicine with legislation that could help fuel its development.

As the debate on healthcare reform heats up in the nation's capital, so too has the emphasis placed on personalized medicine and its promise of better outcomes, lower costs, and greater efficiency. In fact, proposed legislation may help speed new developments in this field focused on tailoring patients' treatments to their individual characteristics and genomics. With Washington wrestling with how to cut costs while increasing coverage, personalized medicine is increasingly figuring in the discussion. The belief is that doctors will no longer have to use a one-size-fits-all approach. Instead, medical care going forward will involve pinpointing the appropriate drug or treatment based on genetic variations, therefore reducing the time and cost associated with the trial and error of medications, treatments, and dosages.

Personalized medicine's possible benefits have not gone unnoticed. Legislators have introduced several bills in the last few years, including a 2007 bill by the then junior Democratic Senator from Illinois Barack Obama, in hopes of creating agencies and working groups to make personalized medicine a reality. Obama's bill sought to create an interagency group to coordinate the policies of federal agencies whose decisions have an impact on the issue.

Representative Patrick Kennedy, a Democrat from Rhode Island, reintroduced the bill during the 111th Congress, adding incentives to lure researchers into the field.

As a senator, Obama had a strong conviction in personalized medicine and it must be continued, says Teresa Deluca, vice president of Personalized Medicine at Franklin Lakes, New Jersey-based Medco Health Solutions, a pharmacy benefits manager. "We recognize we have a tremendous opportunity for what we already had built," she says. "While we look at healthcare reform and want to bring economics to a more bearable level, we see personalized medicine does that. By using genomic information, doctors can prescribe the right dose at the right time."

The Personalized Medicine Coalition, a Washington, D.C.-based non-profit organization made up of a dozen leading pharmaceutical, biotechnology, diagnostics, and information technology companies, has a simi-

Representative Patrick Kennedy reintroduced a personalized medicine bill first pushed by then Senator Barack Obama in 2007.

One of the arguments the coalition makes is that personalized medicine, by introducing efficiency into the system, can lower overall costs. If you get the therapy right the first time, you eliminate the trial and error of medicine.

—Ed Abrahams, executive director of the Personalized Medicine Coalition

lar stance. "One of the arguments the coalition makes is that personalized medicine, by introducing efficiency into the systems, can lower overall costs," says Edward Abrahams, the organization's executive director. "If you get the therapy right the first time, you eliminate the trial and error of medicine."

Abrahams cites Medco as a pioneer in the field and an indication that progress is being made. In 2008, Medco signed a two-year partnership deal with the U.S. Food and Drug Administration to research the role of genetics in the effectiveness and safety of drugs.

"That's a telltale sign that at least one large pharmaceutical manager is looking at the benefits," Abrahams says.

A recent study boosts the case for personalized medicine, Abrahams argues. The study he cites finds that $604 million could be saved annually if the drugs Vectibix and Erbitux were prescribed only to those patients with metastatic colon cancer whose KRAS gene is mutated, because those are the only patients who benefit from the drugs.

But the cost-savings analysis is based on a series of assumptions, not on real world experience, he says. "The challenge we face is to get more economic studies," he says. "It is a real issue because payors, generally absent evidence, are skeptical."

Medco's Deluca believes there are two possible avenues to take personalized medicine from theory to common practice. One way is to find a biomarker to indicate the appropriateness for the use of every new medication placed on the market. Another way, she says, is to conduct additional research on all medications currently on the market to see if such biomarkers can be found. "There's a cost to doing both avenues," she adds.

But with Congress and the White House focusing on reforming the basics of healthcare, personalized medicine could be pushed to the backburner, preventing the practice from moving forward from development and idea to real world application. Advocacy groups and supportive lawmakers must work hard to keep personalized medicine in the minds of those deciding the future of medicine.

— Kristi Eaton

REGULATION

Differing Diagnoses

Controversy is brewing as federal regulators are expected to address calls for greater regulation of diagnostics.

There's been much debate over the role the U.S. Food and Drug Administration should play in regulating the lab tests that guide doctors' decisions about what drugs they use to treat their patients. But whether it's the advocates for a greater role for the FDA or those who argue it's best the agency stay on the sidelines, both sides seem to agree on one point: the very future of personalized medicine is at stake.

Genentech shook up the industry in December 2008 when the bitotech giant filed a citizen's petition with the FDA arguing the

Genentech wants laboratory tests developed in house by testing labs to be subjected to the same scrutiny as test kits sold to labs..

agency should regulate all in vitro diagnostic tests. Genentech wants lab developed tests or LDTs—genetic test produced in house by testing labs—to be subject to the same scientific and regulatory standards as in vitro diagnostics test kits sold to labs. Currently the FDA regulates test kits, but not LDTs.

"The failure to apply clear and consistent standards and regulatory oversight to all LDTs could threaten the public health and serve as a disincentive for the development of diagnostic test kits through FDA's review pathway, thereby potentially undermining the move toward more personalized approaches to healthcare treatment and delivery," Genentech's General Counsel Sean Johnston wrote in the citizen's petition.

The issue is of no small concern to the South San Francisco company, which has since been acquired by Roche. Several of Genentech's products are now associated with the use of diagnostics, many of which have never undergone review by the FDA. These tests are marketed under the Clinical Laboratory Improvement Amendments or CLIA.

Genentech's move didn't just spark questions over the broader issue of the FDA's role in regulating diagnostics. It also drew harsh criticism from some groups, such as the American Clinical Laboratory Association, which represents makers of lab-developed tests. Responding to the Genentech's petition, the group commented to the FDA that implementing Genentech's recommendations would undermine the ability of labs to bring new tests to market and delay patient access to medical advances.

"The petition's proposed approach would inhibit innovation and the application of new advances in testing, just at the time when there is such potential in the areas of personalized medicine and genetic testing," the group's president Alan Mertz wrote in response to Genentech's filing.

The issue of increasing FDA involvement in the regulation of diagnostics had been under discussion long before the Genentech citizen's petition. The issue picked up steam when an April 2008 report from the Secretary's Advisory Committee on Genetics, Health, and Society to the U.S. Department of Health and Human Services concluded there was a gap in oversight of diagnostics. The report said the department needed to address the gap and that the FDA should have a role in doing that.

The key trade group representing diagnostics makers been in discussion with the FDA over its proposed risk-based approach to regulating diagnostics. It argues that the FDA should oversee the safety and efficacy of all diagnostics, whether developed by manufacturers or clinical laboratories. But, it says, the agency should do so based on the risk posed by the use of the results of a given test in patient management. Tests that represent well-established technologies used to detect familiar biomarkers, the group says, should be exempt from needing FDA approval prior to marketing. "From our view this is looking to create a reasonable process for diagnostics," says Khatereh Calleja, associate vice president technology & regulatory affairs for AdvaMed, short for Advanced Medical Technology Association. "This is not to stifle innovation, but to foster it."

Calleja says diagnostics manufacturers as a whole are supportive of a risk-based approach. She says there's a proposal in the works that would support continued innovation in this area, yet still address some of the public health concerns that have been expressed with new emerging genetic tests.

Though AdvaMed's proposal is more comprehensive than the issues of lab developed tests addressed by Genentech, it is worth noting that Genentech calls for FDA to use a risk-based approach as well. It says many LDTs would be considered low-risk and not require significant regulatory oversight. But LDTs used in clinical decision making to determine the use of a particular drug for a patient should be considered high-risk because of the potential danger an patient, the company says. Should the FDA move toward such a plan, it might not be difficult to get the various players on board in principle. The fight, however, will likely turn on how the agency decides to define the risk of a given diagnostic.

— Daniel S. Levine

DEALMAKING

Fellow Travelers

Big Pharma's move toward targeted therapeutics is fueling dealmaking between drug and diagnostics companies.

The promise of personalized medicine—treatment tailored to specific patients—is beginning to change the course of drug development. Instead of aiming for mass-market blockbusters, pharmaceutical and biotech companies are increasingly setting their sights on targeted therapies to treat patient populations with specific subtypes of a disease. Identifying the right therapy for the right patient will rely, of course, on medical tests or "diagnostics," as they're called, to establish the disease subtypes. And the increasing importance of having a diagnostic paired to a therapeutic is expected to lead to a rising number of mergers, acquisitions, and partnerships built around companion diagnostics, a new report shows.

"We think that diagnostics is the tip of the spear in personalized medicine and this trend will continue as there is more proof of clini-

Stephen Little, CEO of DxS, says pharmaceutical companies are beginning to embrace the Rx/Dx model..

cal utility," says Gerry McDougall, principal, Healthcare Advisory Services at PricewaterhouseCoopers and one of the authors of the consultancy's *Diagnostics 2009: Moving Toward Personalized Medicine*. Although the number of such deals fell in 2008 compared to 2007, this was due in part because the industry had to absorb the record number of deals from the previous year, McDougall notes.

Several factors are driving the potential increase in personalized medicine deals. Among them is increased use of biomarkers and assays to identify the group of patients most likely to benefit from a particular therapy. There's also the greater likelihood, with treatments better matching patients, that clinical trials will be successful. This in turn can lead to cost savings as well as a better chance that a therapy can pass muster with an increasingly risk-averse U.S. Food and Drug Administration.

Stephen Little, CEO of Manchester, United Kingdom-based companion diagnostic company DxS, thinks the future looks bright for personalized medicine deals in part because the pharmaceutical industry is recognizing their value. "An important change that we've noticed is that drug companies have moved from the position of really being quite resistant to the idea of using a companion diagnostic to embracing it," he says.

The benefits can be seen throughout the development cycle, experts say. "If you can select patients who are more likely to respond to your therapeutic agent than patients at random, or unselected patients, then you are more likely to have a successful clinical trial," says Joe McCracken, who until recently served as vice president of business development for Genentech. "It requires fewer patients. In addition, I think the FDA is more comfortable when they look at the risk-benefit profile for the drug."

Most pharmaceutical companies look externally to develop companion diagnostics. With the growing acceptance of the value of pairing such a test to a therapeutic, DxS' Little says it's not surprising to see this need driving deals.

Deal pace picked up in the second and third quarters of 2009, with nine deals announced as of mid-August. DxS has been busy, striking a deal with AstraZeneca in early August to develop its EGFR mutation kit as a companion diagnostic for AstraZeneca's lung cancer drug Iressa. DxS is also working with German pharmaceutical company Boehringer Ingelheim to develop an EGFR test as a companion diagnostic for a non-small cell lung cancer therapy before the start of late-stage clinical trials. And, the company has signed agreements with Amgen and Bristol-Myers Squibb to provide an EGFR assay to identify the K-RAS oncogene in colon cancer tumors.

Little says companies are knocking on his door to do companion diagnostic deals, unlike a few years ago when the concept was not well established. "I think a lot of the concerns that drug companies had about just how would a companion diagnostic strategy work have been allayed, because we have seen it working in practice," he says.

For now, the deals driven by companion diagnostics have focused on oncology. The dealmaking trend should continue as more pharmaceutical companies pursue personalized medicine strategies, but it's unclear whether and how soon this trend will move into other areas of medicine.

—Marie Daghlian

POLICY

Boon or Bust

Lawmakers are taking note of the potential benefits of comparative effectiveness research, but will it speed or impede the development of personalized medicine treatments?

Less than six months after the federal stimulus package allocated $1.1 billion for comparative effectiveness research, two senators introduced a bill to establish a private, nonprofit corporation to study the most cost-effective and beneficial healthcare treatment programs. But some fear the increased focus on comparing what treatments offer the most benefits

for the least cost could threaten recent gains in the field of personalized medicine. The worry? Treatments tailored to a specific patient's characteristics and genomics might get short shrift if policymakers are focused on cutting healthcare expenses across the board.

Under the American Recovery and Reinvestment Act passed by Congress in February, the funding for comparative effectiveness research will be spread across several federal agencies. In June, Democratic senators Max Baucus and Kent Conrad introduced the Patient-Centered Outcomes Research Act of 2009, which would establish a Research Institute to assist patients, clinicians, purchasers, and policymakers to find the best methods to diagnose and treat health conditions.

"The goal is to provide physicians, patients, healthcare workers, and hospitals, everyone involved, better information to guide medical care, so it might mean comparing a surgical procedure to a medication or comparing multiple medications," says Alan Garber, director of Stanford University's Center for Health Policy and Center for Primary Care and Outcomes Research.

For their part, federal officials and personalized medicine advocacy groups say there's no reason a shrewder look at the cost-benefits of certain treatments and therapies would threaten the gains in tailored medicine. In a June report to President Obama and Congress, the government body established under the recovery act noted the important strides the field has made in making medical care more precise and effective. Comparative effectiveness research can work hand in hand with personalized medicine, the body says. Not only could it identify which interventions and strategies work best on average, but it would also help identify how unique patient groups respond differently, the group says.

"In some cases, different existing therapies may be identified as most effective for specific subgroups," the report says. "In other cases, [comparative effectiveness research] may help to identify significant sub-groups for whom effective therapies do not yet exist. [Comparative effectiveness research] may also help steer research efforts toward the development of products and strategies for areas of significant need."

The Personalized Medicine Coalition, a non-profit organization made up of a dozen leading pharmaceutical, biotechnology, diagnostics, and information technology companies, thanked Senators Baucus and Conrad for the legislation and incorporating language that leaves room to recognize the value of therapies tailored to address differences between different patients' genetics. "We're lobbying hard to make sure Congress doesn't lock us into a one-size paradigm," says Edward Abrahams, the organization's executive director.

The possibility that the research favors more universal as opposed to individual treatments is one concern. There's also the question about what happens with the research results. "One of the big challenges, after research is completed, is how do you make the leap from presenting results in clinical and scientific journals to make it available in a way the ordinary consumer can understand and make it useful?" Garber says. "So one of the challenges is to make sure there is some structure in place."

Several conservative lawmakers and talk show hosts have been outspoken about their opposition to comparative effectiveness research, saying it will essentially ration healthcare and fail to take individual needs into account. But Garber disagrees. Writing in the *New England Journal of Medicine*, Garber says that "far from impeding personalized medicine, [comparative effectiveness research] offers a way to hasten the discovery of the best approaches to personalization, providing more and better information with which to craft a management strategy for each individual patient."

At a time when many in Washington are focused on finding ways to cut spending on healthcare, it's not surprising that some would see comparative effectiveness as a blunt tool to cut spending at the expense of patient access to new drugs. But, if done right, it's also an opportunity to both test and demonstrate the value of personalized medicine therapies.

— Kristi Eaton

Alan Garber, director of Stanford University's Center for Health Policy, says personalized medicine and comparative effectiveness research can work hand in hand.

A Diagnosis of Deals

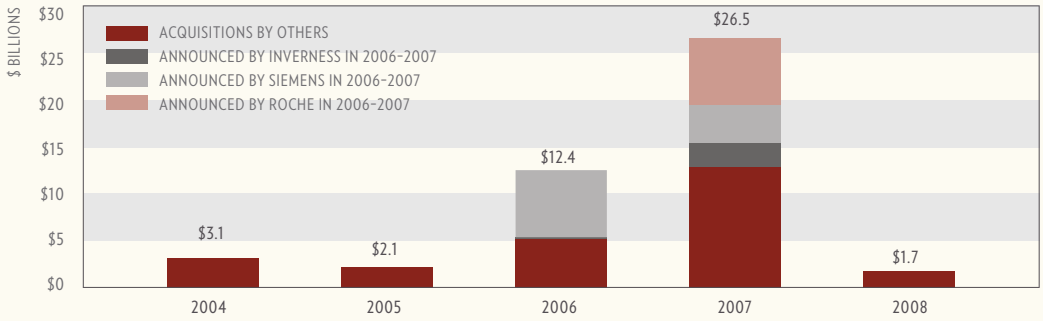
Even though growing interest in personalized medicine has been driving deals in recent years, 2008 actually saw a significant drop in deal activity in the sector, according to PriceWaterhouseCoopers. While the number of M&A deals involving in vitro diagnostic companies reached 51 in 2008, it fell short of the 84 deals announced the previous year. PwC attributes that to the fact that companies were busy digesting their acquistions from 2007, a year of unusually high activity. The contrast is even more dramatic when deal values are compared. The value of M&A transactions for the sector reached $1.7 billion for 2008, a fraction of the $26.5 billion in transactions announced the previous year.

One area to watch is partnerships between pharmaceutical companies and diagnostic makers as Big Pharma focuses increasingly on targeted therapeutics that treat patients with certain subtypes of a disease. These drugs are often married to diagnostics that can identify for which patients their use would be appropriate. PwC say pharmaceutical companies announced seven partnerships with diagnostics companies in 2008 to develop a companion diagnostic for a therapeutic. This represents a significant drop from the 14 collaborations announced in 2007, but the firm notes there is no clear up or down trend over the period 2004–2008. While PwC says companion diagnostics partnerships with pharma have yet to become an established industry practice, industry players say the trend is moving faster than it appears because pharmaceutical companies often don't announce these deals with early-stage projects.

—Daniel S. Levine

NUMBER OF ALL M&A DEALS IN THE IN VITRO DIAGNOSTIC SECTOR, 2004-2008

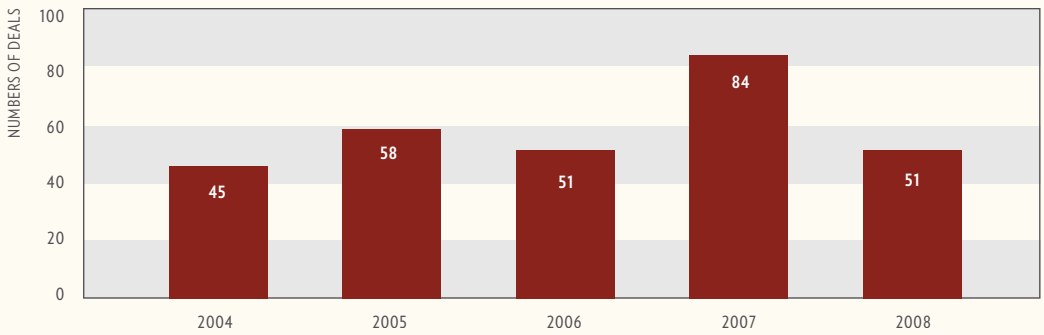
Several big dollar deals bolstered the numbers in 2007.



SOURCE: PRICEWATERHOUSECOOPERS; *DIAGNOSTICS 2009: MOVING TOWARDS PERSONALIZED MEDICINE*

VALUE OF DISCOLSED M&A DEALS IN IN VITRO DIAGNOSTICS SECTOR, 2004-2008

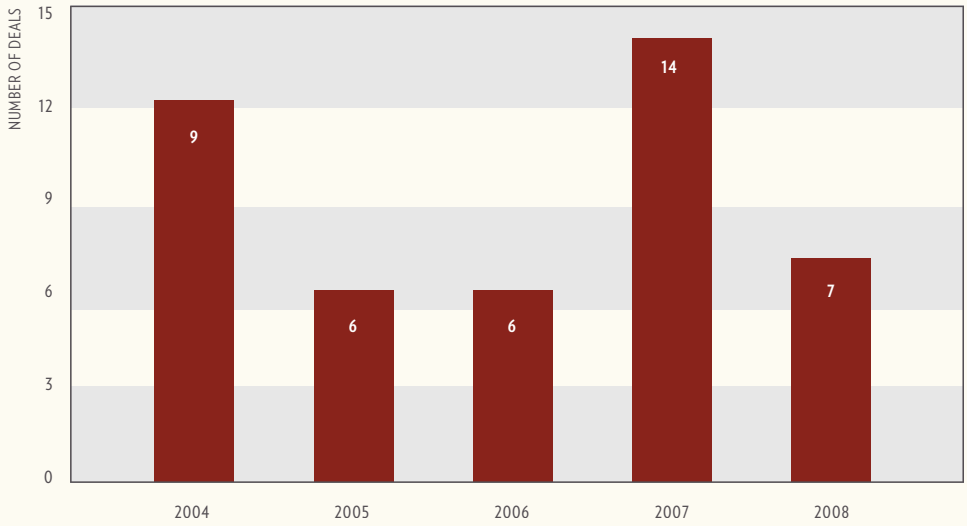
Activity fell in 2008 as the acquirers digested deals from an active 2007.



SOURCE: PRICEWATERHOUSECOOPERS; *DIAGNOSTICS 2009: MOVING TOWARDS PERSONALIZED MEDICINE*

COMPANIION DIOGNOSTICS PARTNERSHIPS WITH PHARMA, 2004-2008

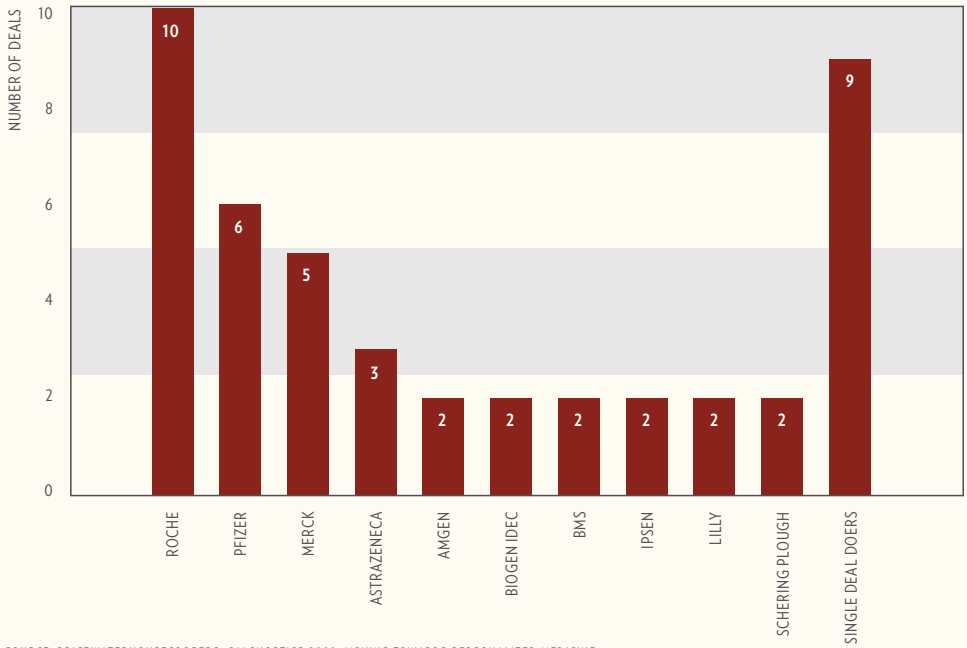
Diagnostics for pairing with cancer drugs generated strong interest among pharamceutical companies.



SOURCE: PRICEWATERHOUSECOOPERS; *DIAGNOSTICS 2009: MOVING TOWARDS PERSONALIZED MEDICINE*

COMPANION DIAGNOSTICS DEALS BY PHARMACEUTICAL PARTNER, 2004-2008

Roche was the most aggressive dealmaker in the area.



SOURCE: PRICEWATERHOUSECOOPERS; *DIAGNOSTICS 2009: MOVING TOWARDS PERSONALIZED MEDICINE*

Let's Make a Deal

There has been a wave of partnering and M&A deals during the past 18 months as companies gear up to take advantage of the evolving new healthcare paradigm of personalized medicine. The $4.66 billion in global M&A transactions in 2008 was dominated by the $3.4 billion acquisition of Ventana Medical Systems by Roche. Another deal of note was Inverness Medical's $580 million acquisition of Third Wave Technologies.

Year-to-date there hasn't been any blockbuster deals in 2009, but the transaction value has reached $761 million. Deals of note in 2009 include: Gen-Probe's $136 million acquisition of Tepnel Life Sciences, a rapidly growing molecular diagnostics company based in the UK; and medical testing giant LabCorp's $155 million purchase of Monogram Biosciences. The acquisition expands LabCorp's presence in personalized medicine.

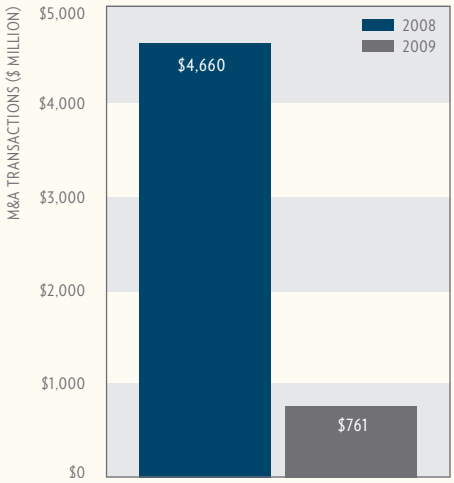
The number of alliances between diagnostics and pharmaceutical companies will continue to rise because of the growth of personalized medicine, according to a report from PricewaterhouseCoopers. The report, *Diagnostics 2009: Moving Towards Personalized Medicine*, argues that the drive towards personalized medicine can be attributed to several factors, including regulatory agencies that are introducing requirements to test for certain biomarkers prior to prescribing certain drugs.

The Burrill Report (www.burrillreport.com) has documented more than 30 such partnership deals established in 2009 to date. Examples include:

GlaxoSmithKline and Enigma Diagnostics have signed a worldwide agreement to develop and supply the first point-of-care diagnostic influenza tests to identify specific influenza virus strains using its real-time polymerase chain reaction technology platform, the Enigma ML. The partnership will enable GSK and Enigma to develop the Enigma ML to

PERSONALIZED MEDICINE M&A TRANSACTIONS

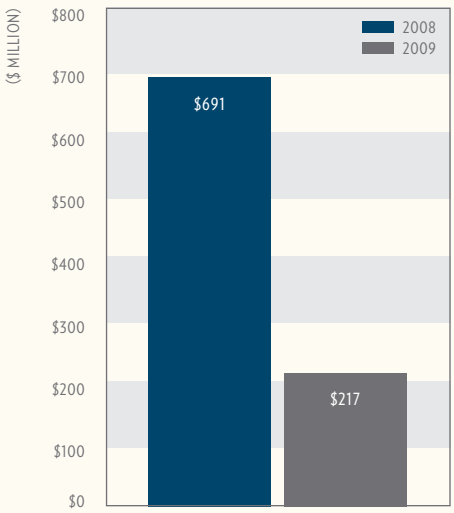
Roche's $3.4 billion buy of Ventana boosted 2008.



SOURCE: *THE BURRILL REPORT*

VENTURE CAPITAL FLOWS TOO

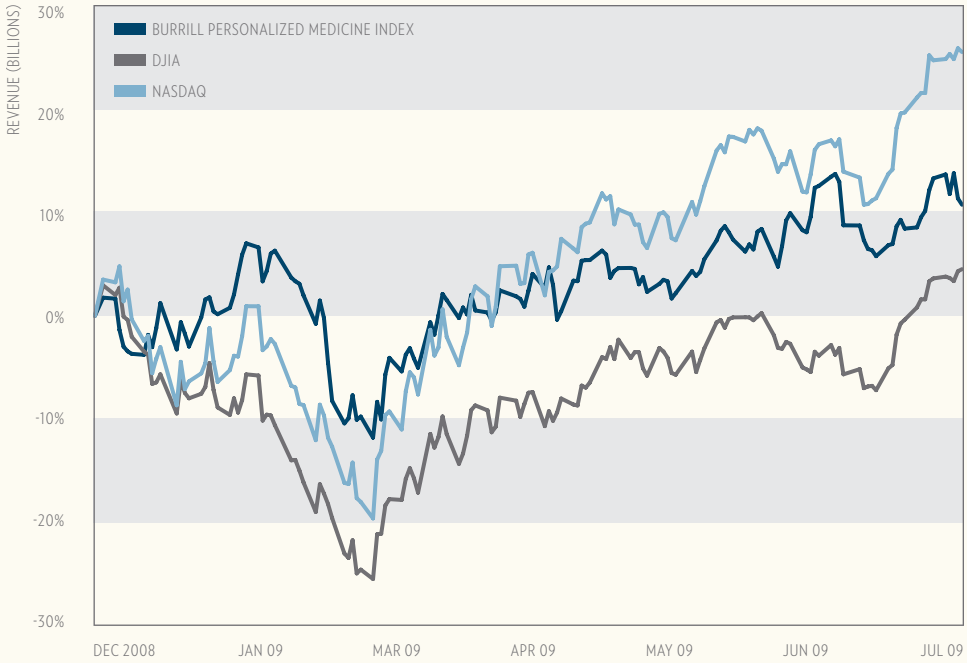
Investment in personalized medicine slows in 2009.



SOURCE: *THE BURRILL REPORT*

PERSONALIZED MEDICINE INDEX

The sector has a solid perfomance in the first half of 2009.



SOURCE: *THE BURRILL REPORT*

deliver fully-automated results from swab samples in less than 60 minutes at the point of care and to the same accuracy standards as reference laboratories. This will mean that patients can be tested for specific influenza subtypes in the community and receive appropriate treatment rapidly. A trial involving working prototypes of the ML system with frontline healthcare providers across Europe will commence in the fourth quarter of 2009. Launch of Enigma ML is anticipated in early 2011, subject to successful clinical trials and regulatory approval.

UK-based diagnostics company DxS is working with AstraZeneca to provide a diagnostic test for use with its lung cancer drug Iressa. A mutation in the epidermal growth factor receptor, or EGFR, occurs in about 10–15 percent of lung cancers in non-Asian patients, and it is these tumors the drug works best on. DxS said its TheraScreen EGFR29 diagnostic kit will be used to screen potential Iressa patients for the mutation.

More VCs are jumping into personalized medicine too. According to Thompson Reuters the number of U.S. VCs investing annually in diagnostics and genomics has almost doubled in the past five years. Last year, for example private diagnostics and personalized medicine focused companies around the world collectively raised almost $700 million in venture capital (approximately $470 million in the United States). Even in today's economically challenging times companies working in the personalized medicine space have raised $217 million this year and are on target to top the $400 million mark.

One of the beneficiaries of the surge of investor interest in the sector is Menlo Park, California-based Pacific Biosciences, a company pioneering the development of a transformative DNA sequencing technology. It raised $68 million in financing in August 2009 making a total of $188 million that has been invested in the company since last summer.

—Peter Winter

Summer Sizzle

Biotech was hot this summer as positive drug data, strong sales and earnings, and partnering and M&A deals drove share prices higher. As a result, the Burrill Biotech Select Index posted a solid gain of 6.5 percent in the June to August period, mirroring the major indicies. The Dow Jones Industrial Average jumped 12.4 percent and the Nasdaq Composite Index rose 9.5 percent during the same period as they recordered their best summer performances in years.

The Burrill Personalized Medicine Index remained unchanged this summer. Becton Dickinson's shares fell 3 percent in July after it provided lower guidance for 2010. Illumina, which makes products that analyze genes and biological functions, also dropped 9 percent despite posting a second-quarter profit that was almost twice that of the comparable quarter a year earlier.

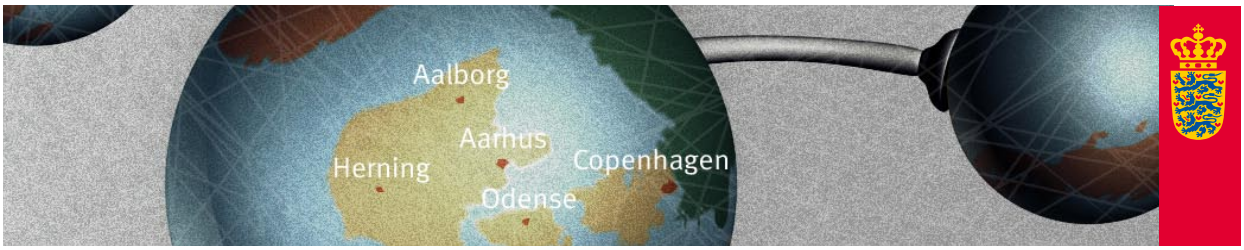
Personalized medicine is an emerging trend. The Burrill Personalized Medicine Index is up a healthy 14 percent year-to-date as investors have generally been intrigued with companies in the personalized medicine and genetic analysis space. The combination of new product introductions, recent acquisitions, and revenue from partners has expanded the business of Affymetrix, which saw its shares post a whopping 30 percent jump in value during the summer. The company's shares have been on a roll in 2009 and up almost 160 percent since January.

—Peter Winter

BIOTECH INDICES

Index	12/31/07	12/31/08	6/30/09	8/31/09	% Change (Month)	% Change (Year)
Burrill Biotech Select	331.52	300.33	294.09	309.76	5.33%	3.14%
Burrill Large Cap Biotech	437.71	379.7	424.71	450.36	6.04%	18.61%
Burrill Mid-Cap	201.89	139.39	173.97	176.26	1.32%	26.45%
Burrill Small Cap	137.6	78.35	82.51	100.56	21.88%	28.35%
Burrill Genomics	104.29	59.69	65.73	122.84	86.89%	105.8%
Burrill Personalized Medicine	**126.82**	**79.63**	**90.53**	**90.73**	**N/C**	**13.95%**
Burrill BioGreentech	158.66	106.12	133.21	142.17	6.73%	33.97%
Burrill Diagnostic	159.43	138.3	131.47	139.58	6.17%	0.93%
NASDAQ	2652.28	1577.03	1835.04	2009.56	9.48%	27.40%
DJIA	13264.82	8776.39	8447	9496.28	12.42%	8.200%
Russell 2000	766.03	499.95	508.28	572.37	12.61%	11.49%
Amex Biotech	786.5	647.15	697.17	925.56	32.76%	43.02%
Amex Pharma	338.52	272.84	262.11	283.53	8.17%	3.92%

SOURCE: *THE BURRILL REPORT*



Denmark – taking medicine personal

Denmark, with its strong historical scientific base within drug development, is embracing progress aggressively and has identified personalized medicine as key to future health care.
One of the central reasons for the Danish stronghold in the field of personalized medicine is the excellent collaborative research efforts between basic research institutions, academic and commercial researchers and a number of highly skilled and very strong diagnostic companies.

Danish universities and hospitals are home to leading research groups within various technologies that can be applied in personalized medicine. Furthermore, Danish academia is world leading within research into cancer, CNS, infectious diseases and diabetes, which are therapeutic areas that are very promising in relation to personalized medicine.

Finding the key to treating cancer…

To exemplify, a significant part of the chemotherapy, which is used to treat cancer patients, has insufficient power and cancer medicine is expensive and requires considerable resources to develop. A Danish interdisciplinary research team, consisting of doctors, veterinarians, biologists and biochemists, have found an important key to tailor the cancer treatment in order to
work optimally for the individual patient.

Access to quality data, registers, and bio banks…

Several diagnostic companies have chosen to locate in Denmark, leading the way in developing technologies and specific diagnostic kits for use in personalised medicine. Furthermore, Danish companies hold a strong position in diagnostics, particularly in diagnostics based on disease causes rather than disease symptoms – a key factor in personalised medicine. Another important factor for especially R&D within personalized medicine is that Denmark is unique in its access to data through comprehensive data registers available (central personal registration (CPR) number, the National Patient Registry, health economic statistics and diagnosis registration in general practice (in process) making it possible to combine and reference data across different areas.
For e.g. risk evaluation this is crucial as it provides unique access to continuously updated and accurate information in risk control. In Denmark, it is possible to combine various registers like the personal identification number with clinical trials, which means that it is possible to connect a range of personal information like address, income, gender, age etc. with a sample from a biobank. As an example, the Danish Cancer Registry contains information and biological samples of all Danish cancer patients from 1942 to present-day. This is an internationally unique resource in Denmark, which gives the possibility to follow an entire nation's development of cancer.

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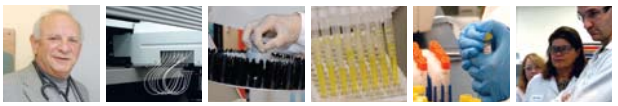


Gazing into the Future

Tethys Bioscience brings an affordable diagnostic to market that promises to help physicians fight diabetes before the disease strikes their patients. But it's unclear whether doctors and payors are ready to embrace it.

Story and Photos by Daniel S. Levine

When a CEO quotes Niccolo Machiavelli's *The Prince*, it's probably wise to keep your distance. But biotech executive Mickey Urdea thinks the political theorist was right on the mark, not about it being better to be feared than loved, but about disease. Writing about consumption—the potentially fatal, contagious disease now known as tuberculosis—the Italian philosopher said "in the first stages it is easy to cure though hard to detect, but with the progress of time, if not detected or treated, consumption becomes easy to detect, but hard to cure." Machiavelli was using a metaphor for affairs of state, but for Urdea, the words reflect a business plan focused on the value of identifying disease before it manifests itself.

Urdea's Tethys Bioscience began to take shape in 2005. Backed with seed funding from the venture capital firm Mohr Davidow Ventures, the Emeryville-based diagnostics company began an exercise to zero in on diseases that Urdea says had both enormous health and economic impacts. That led the company to target type 2 diabetes, a chronic condition in which the body fails to produce adequate amounts of insulin or grows resistant to its effects.

The direct and indirect cost of the disease, which can lead to heart disease, blindness, and the need for amputations, grew to $174 billion in 2007, according to the American Diabetes Association. Mindful of the disease's toll on society, Tethys developed its first in a line of predictive diagnostics under the PreDx (pronounced "predicts") line, the PreDx Diabetes Risk Test. In June 2008, some three years after its founding, Tethys began selling the test.

While many other diagnostic companies at the vanguard of personalized medicine look at patients' genetics, Tethys instead looks at a series of biomarkers in the blood to determine the likelihood that someone will develop type 2 diabetes within five years. Unlike the genetic make-up of a patient, which doesn't change, Urdea says the information provided by the PreDx test offers insight into biological changes that can signal the onset of diabetes before it happens. This ability gives doctors a way to identify high-risk patients in time so that lifestyle changes and drug therapies can be used to prevent development of the disease.

"We're the poster child of preventive, personalized medicine," says Urdea. "There hasn't been a lot of focus on prevention until now. We think this is the right way to go because it is going to save the most money and make the greatest impact. There's just no way of having a bigger impact on a disease than preventing it."

Though there are many people at risk for diabetes, it is difficult to identify through traditional means who will actually develop the disease. In the United States, there are 57 million people over the age of 40 with a body mass index greater than 25. But of this population, only 5 percent will actual become diabetic within five years, the company says. Urdea and his team decided to look at levels of certain proteins and other substances in the blood to see if they could identify those who are likely to develop the disease within that time. The goal was to help doctors focus on interventions for those patients.

Edward Kersh, chief of cardiology at St. Luke's Hospital in San Francisco, began using the test in June. When the PreDx test shows a patient to be at high risk for developing diabetes, he says he refers them to the hospital's diabetes clinic for education and to help alter their lifestyles. Traditionally, though, he says getting patients to alter their lifestyle is a challenge—only about 10 percent do so over the long term. Though it's too early to tell, he thinks the PreDx test results will prove to be powerful motivators. "When the patient sees it in black and white on a piece of paper and reads it, they say, 'You mean I'm going to have diabetes in five years? What can I do about it?'" says Kersh. "'You can do X, Y, and Z, lose weight, exercise more.' They become very motivated to do it."

But the value of the test goes beyond sifting through those patients who appear to be at high risk. Recently, Kersh was treating a 50-year-old Korean man who suffered from high blood pressure. He described the man as lean and fit. Kersh successfully brought the man's blood pressure under control. The man, he says, was not someone who appeared to be at risk for diabetes. But when Kersh noticed his blood sugar was a "tad elevated," he decided to give him a PreDx test. The man scored 8 out of 10, a score that signifies a high risk of developing the disease within five years. Kersh says the man has since made lifestyle changes to address the issue.

"With this guy, no one would have a clue," says Kersh. "You'd take a look at him and say, 'He's not a candidate for diabetes,' until he goes into a diabetic coma."

The researchers at Tethys began with a list of more than 260 substances in the blood that studies suggested could be indicators of the

Tethys Bioscience's Associate Director of Clinical Lab Operations Marianne Winell overseas day-to-day operations of the company's diagnostic lab in Emeryville, California.

Edward Kersh, chief of cardiology at St. Lukes Hospital in San Francisco, says the PreDx test results have proven to be powerful motivators to get patients to change their diets and lifestyles.

development of diabetes. They pared the list down to 89. Then they examined the presence of these substances in more than 6,000 blood samples from patients followed for at least five years, about 250 of which developed diabetes during that time. In the end, the team identified a set of seven biomarkers—adiponectin, C-reactive protein, ferritin, fasting glucose, insulin, interleukin-2 receptor alpha, and HbA1c—that the company says together provides a reliable indicator of the likelihood that someone will develop diabetes within five years. What was perhaps surprising is that well known biomarkers for diabetes such as hemoglobin A1C and insulin contribute less to the PreDx algorithm than others, such as the iron transport protein ferritin and a receptor involved in inflammation known as il-2R Alpha. One benefit of these biomarkers is that there were long established lab tests for most of them.

Tethys Bioscience CEO Mickey Urdea holds up a sample PreDx Diabetes Risk Test report. Based on the level of seven biomarkers in the blood, the test scores patients on a scale of 1 to 10 to determine their risk of developing type 2 diabetes within five years.

"You really don't want an esoteric test," says Bill Ericson, a managing partner at Mohr Davidow Ventures and member of the Tethys board. "You want a technology that's generally been applied previously because it takes a lot of issues of validation off the table. People aren't worrying about is that platform appropriate? How do we validate the platform? What does the FDA think of the platform? That's made a big difference with how quickly they've been able to get to market. They've tried to simplify everything at the point of care and the point of analysis."

Indeed, the company has not faced the same hurdles getting reimbursed for its diagnostic as emerging genetic test makers have faced. Today the company sells its test for $465 for each kit. Even though reimbursement codes don't yet exist for its diagnostic Tethys is able to use so-

called "code stacking" to charge for the components that make up its test because most of the tests are already in use.

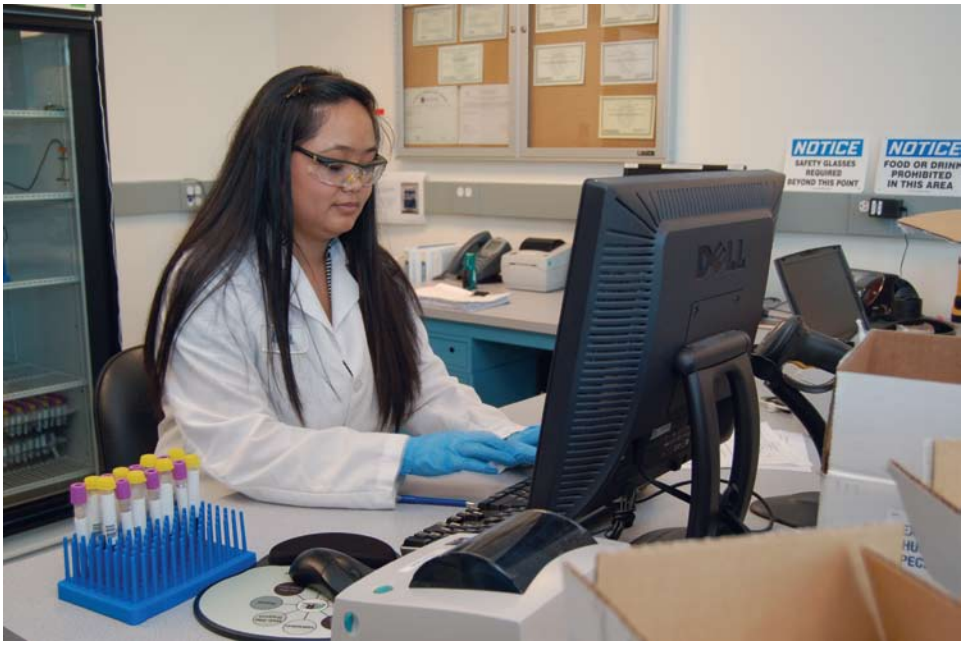
In essence, though, the company does not yet get paid for its intellectual property—the algorithms that underlie that scoring of the test and provide a simple score between 1 and 10 to communicate the risk of developing the disease to a doctor and patient. Ericson says the price the company is getting today is an "okay price." But, he adds that whatever the price is will evolve from the test's use and the economic value it creates in the improvement in patients' health. Still, the company will need to convince payors that its test is not only a reliable predictor, but that it also provides information that doctors and patients can act on, translating the results into healthcare savings.

For now, though, the biggest challenge for Tethys is letting doctors know about the test's availability. Urdea says doctors have long faced the problem of how to identify patients at high risk of diabetes without a proper tool. As a result, they are quick to understand the test's utility, he says. Tethys is being selective in the doctors it is contacting. It's focusing on primary care doctors who are aggressive about wellness and prevention.

But with the country's debt spiraling out of control, healthcare reform is increasing the pressure to find ways to cut costs. Tethys is betting that a lot more employers, payors, and doctors will become focused on wellness and prevention in this new reality for healthcare—and that the PreDx test will allow them to do so effectively. TJOLS

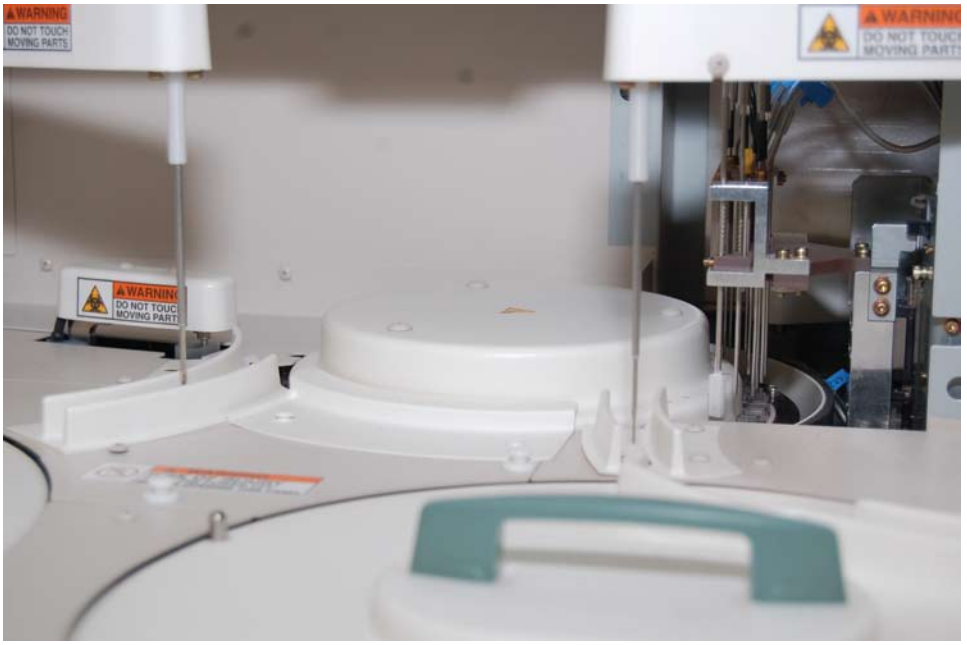
Tethys Bioscience Reserach Associate Glen Hein fine tunes a machine that will automate the last of seven tests that make up the PreDx Diabetes Risk Test. It is the one test in the process now that lab workers carry out by hand.

Tethys Bioscience Lab Assistant Raquel Gimutao (*above*) opens blood samples sent to the lab for analysis. This begins the process of analyzing patient samples.



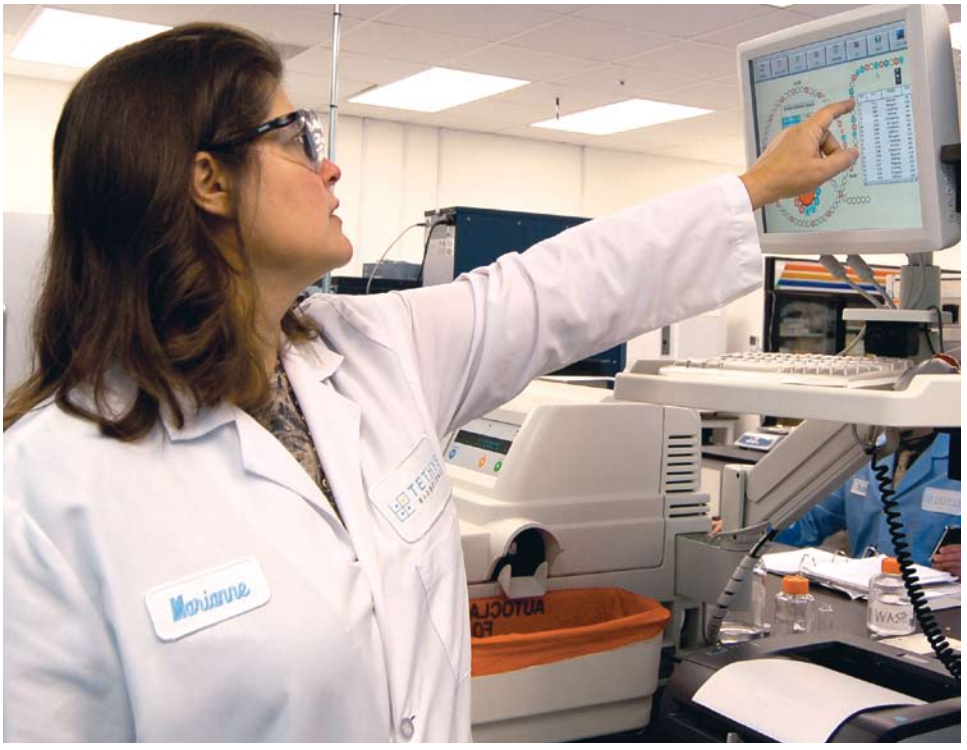
Once samples arrive at the Tethys lab, Gimutao enters information about the sample into the lab's computer (*right*) so it can be tracked through the analysis process.

Amalia Ocampo (*above*), a Tethys Bioscience clinical lab scientist, places blood samples in a machine that performs the first three of seven tests that make up the company's PreDx Diabetes Risk Test.



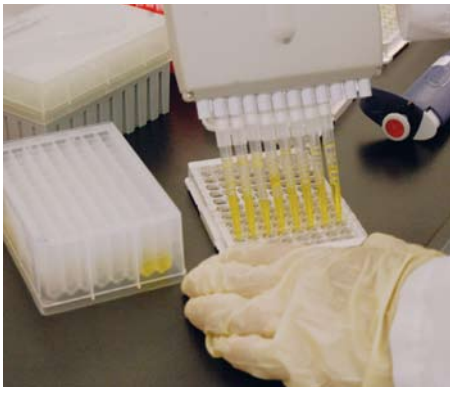
Probes on an analyzer (*left*) pull blood samples from vials and run a set of diagnostics on them in an automated process.

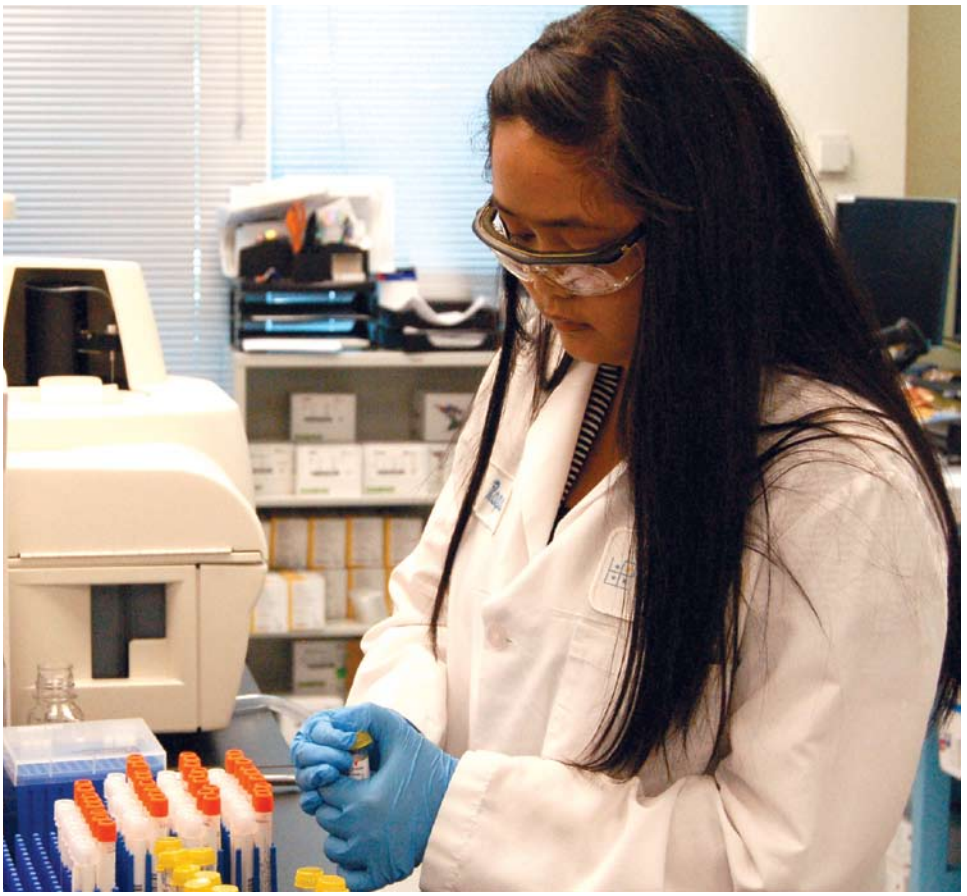
Associate Director of Lab Operations Weinell (*right*) checks a computer screen that provides constant monitoring of quality control of the tests performed in the lab.



Weinell checks a print-out of the ongoing tests being performed at the lab as they are completed (*below*).

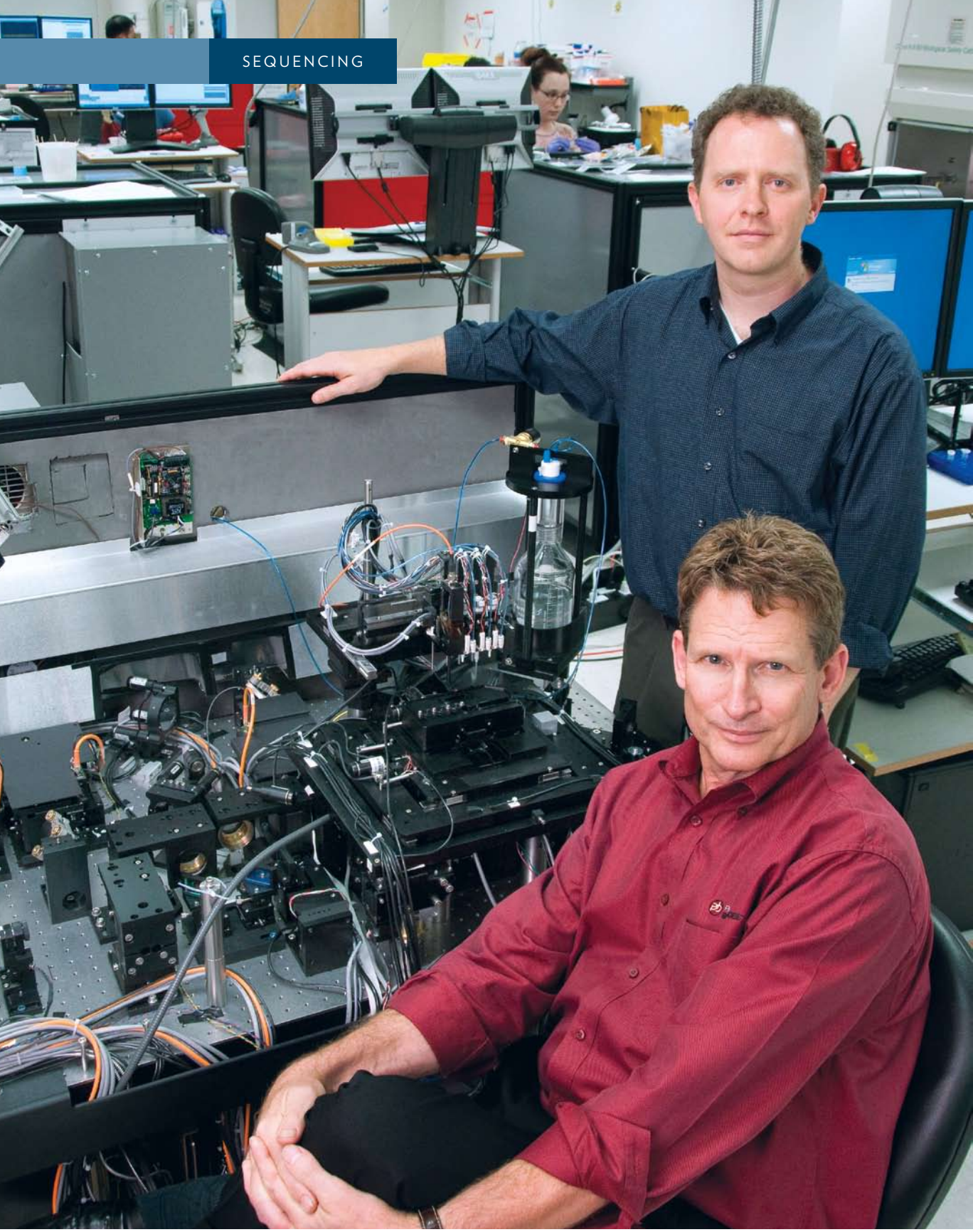
Patient samples are placed in an assay for analysis of adiponectin, a hormone produced by fat cells that promotes sensitivity to insulin. Patients with low levels of this hormone have a higher risk of developing type 2 diabetes (*opposite*).





Lab Assistant Gimutao prepares blood samples left over from testing for long-term storage in the company's freezers (*left*).

Cindy Chan, (*left*) a Tethys Bioscience Lab Assistant, places a test results in an envelope for mailing to the doctor who ordered it. Test results are also automatically faxed when testing is completed.



Speed Freaks

The race is on to sequence whole genomes for $1,000, but already companies are talking about shattering that mark and making scans no more expensive than routine procedures such as blood and urine tests.

By Daniel S. Levine

On May 6, 1954, at a track meet in Oxford, U.K., Roger Bannister ran a mile in 3 minutes, 59.4 seconds. At the time, many had considered running a mile in under four minutes an impossible feat. Some viewed it as an insurmountable psychological barrier, if not one of physics itself. In fact, the breaking of the four-minute mile is still considered among the greatest sports accomplishments.

If the sequencing of a whole human genome–determing an individuals entire genetic code–for $1,000 were the equivalent of running a four-minute mile 55 years ago, think of Hugh Martin as some kid in the early 1950s boasting that he would soon run a 40-second mile—and mean it.

The CEO of Menlo Park, California-based Pacific Biosciences has that jocky kind of swagger, typical of executives who have risen to the top in Silicon Valley. A veteran of the telecom and computer gaming industry, Martin was recruited by the venture capital firm Mohr Davidow Ventures to head Pacific Biosciences in 2005. The pick was a recognition that so-called third generation sequencing, new approaches to sequencing that promise to one day reduce the time and cost of sequencing to once unimaginable levels, was as much an information technology challenge as a biochemical one.

Built upon technology initially developed at Cornell University, Pacific Biosciences expects to go to market by the second half of 2010 with a device that can leave previous sequencing machines in the dust. The goal is to sequence 3 base pairs–the pairs of molecules that make up the rungs of the twisted DNA ladder–per second. With improvements to reagents, the chemicals used to make possible the reading of the DNA, the device will eventually be able to complete 10 base pairs a second. That compares to second-generation machines today that sequence at the relatively plodding rate of just a base pair per hour, Martin says.

Eventually—about three years after the introduction of the first machine—Martin expects to produce a follow-up device that will be able to sequence a genome at a rate of 50 base pairs a second and at a cost of $100. "When you go to the doctor and the doctor fills out the form and checks off blood, urine, test this, test that, there isn't anything on that form that cost more than 150 bucks," says Martin. "If we're going to have a box that says 'sequence,' we are going to have to get it to the point where it's in that class of price."

When you go to the doctor and the doctor fills out the form and checks off blood, urine, test this, test that, there isn't anything on that form that cost more than 150 bucks. If we're going to have a box that says "sequence," we are going to have to get it to the point where it's in that class of price.

—Hugh Martin, CEO, Pacific Biosciences

In the genome-sequencing field, it can be difficult to discern the true merit of a boast. Thank goodness there may be one way to gauge the technical and cost accomplishments of various efforts. It is the Archon X Prize, a $10-million bounty being offered to the first team to successfully sequence 100 genomes (the full set of genetic material consisting of paired chromosomes, one from each parental set totaling

Pacific Biosciences CEO Hugh Martin (*seated*) with company founder and CTO Stephen Turner surround a prototype of their sequencer. The company expects its technology in the next several years to sequence an entire human genome for $100.

Clifford Reid, CEO of Complete Genomics, is taking a different approach than his competitors. Rather than seeking to sell instruments and reagents, Complete Genomics is pursuing a service business model.

It will turn out one of our major costs will be electricity for running our data center. The reagents cost is on its way to zero and the major cost will be electricity.

—Clifford Reid, CEO, Complete Genomics

6 billion base pairs) in 10 days, for less than $10,000 a genome. So far, the prize has gone unclaimed. Although, at least seven teams have registered to vie for it. The prize sets a high bar. The winner must also demonstrate accuracy of no more than 1 error in 100,000 base pairs, with sequences accurately covering at least 98 percent of the genome. The completed results will need to include all insertions and deletions, all rearrangements, and other technical requirements aimed at measuring the accuracy and completeness of the sequencing. To date, none of the teams has successfully completed the task, let alone declared they were prepared to try.

The notion of the $1,000-genome began to take shape before the completion of the mapping of the first human genome, according to Jeff Schloss, program director, technology development coordination at the National Human Genome Research Institute. As best as Schloss can tell running through documents at the institute, the first discussion of the $1,000 genome took place in December 2001 during a planning workshop held by the National Human Genome Research Institute at the Arlie House in Warrenton, Virginia. There are staff notes that it had been proposed as a topic for discussion, but the record is unclear by whom. The institute, looking at the completion of human-genome sequencing within reach, had invited researchers, biopharmaceutical executives, and others with a stake in the emerging field of genomics. On the plate was identifying the problems the emerging science could solve as well as the tools that would be needed to do so. The institute at the time set goals for the next five to eight years.

Schloss admits that eight years ago, a $1,000 genome was a "completely audacious" goal. He estimates that the cost of sequencing the first human genome—the genome itself excluding other costs related to the Human Genome Project—was about $500 million. It took a year. "The idea that one could sequence genomes for much, much less money than it cost was an intriguing one," he says. "I'm not sure anyone believed it could be done. To the extent that there was a discussion of the realities, people thought it would take between 10 and 25 years to get there."

But the goal of the $1,000-genome is not an arbitrary one. It reflects a reality that the mapping of a single human genome wasn't by itself going to provide the insight into human disease contained in DNA. To do that requires sequencing hundreds of genomes from people with a specific disease and comparing their genomes to the genomes of healthy people. Sequencing so many genomes at a cost of $500 million—or even $100,000 as was the cost a few years ago—would be economically prohibitive.

That's why the ability to sequence genomes for $1,000 a piece, in simple terms, is a game changer. It promises to allow researchers to ask questions about biology and medicine in a completely different way. "Having one, you say 'okay, this is what a human genome looks like,' says Schloss. "What you really want to be able to do is look at the genomes of many individuals, particularly of people who have a particular disease, and compare that to people who don't have that disease and see what's different. That's what you really want to see. And then you want to do that for all the major diseases."

That's precisely what Complete Genomics hopes to do. Already, the Mountain View, Cali-

fornia-based company says it is offering whole genome scans to customers seeking to scan eight or more genomes at a price of $5,000 a piece. Unlike its competitors, Complete Genomics' business model is not to market instruments and reagents. Instead, it is pursuing a service model where customers send samples to its scanning facility and it returns the completed data. To date, the company has signed up a dozen customers, but it eventually envisions having scanning and data facilities throughout the world. "The key distinguishing characteristic between us and the other guys is scale," says Clifford Reid, the company's CEO. "We're built for scaling up. Everything we do is for scale."

The company's vision is to work with partners, such as countries, research organizations, or pharmaceutical companies to build sequencing centers over the next five years. Reid says he expects to open about 10 of these facilities around the world. Collectively, those 10 sequencing facilities over five years will have the capacity to sequence about 1 million genomes. "The way to think about 1 million genomes is that's 1,000 people in each of 1,000 disease studies," he says. "That's all of the important disease right there. In the next five years, we can understand the genetic basis of all of the important human diseases and that's going to change medicine."

Though the sequencing field is advancing very rapidly, it's difficult to pinpoint its exact progress in part because of the dizzying pace of change, and in part because people, quite simply, play fast and loose with the numbers. When it comes to sequencing costs, some focus on the cost of the reagents used while others include labor and amortization of equipment in the calculation. What is often left out of such calculations is the quality of the end result.

By the time the first human genome was mapped, improvements to the technology shrunk the cost of sequencing from to an estimated $10 million from $500 million. But there was wide belief that the first generation sequencing technology known as Sanger sequencing, despite room for improvement, would never be fast and cheap enough to make sequencing affordable for broad use. The method, named for its developer Fred Sanger, uses the molecular building blocks of DNA and the enzyme DNA polymerase to clone fragments of DNA. The cloning of the DNA fragments is repeatedly halted so that fragments of varying lengths are cloned. Flourescent markers identify the location of the so-called nucleotides consisting of adenine, cytosine, guanine, and thymine. The fragments are sorted by length and then powerful computers assemble the data to stitch the information into a complete genome.

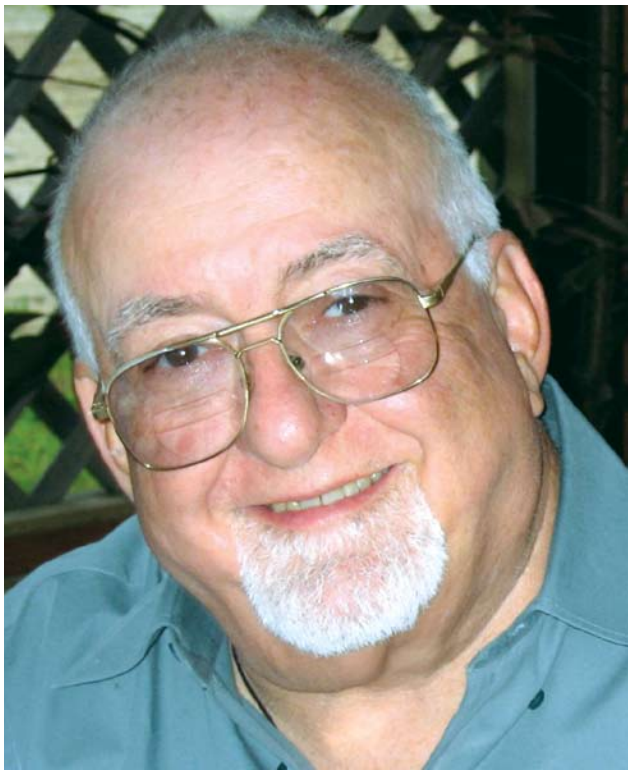
The second-generation technology involves the use of massively parallel sequencing carrying out thousands or millions of DNA fragments at once. It uses smaller fragments and has made sequencing more of a computing challenge. It has driven the cost down by most estimates to below $100,000 a genome.

Mark Stevenson, president and COO of Life Technologies, is betting the company's size and reach will give it a big advanage over a new generation of start-ups when it comes to being commercially successful.

This is a young industry. We're just getting going. You are going to attract some smaller, newer players into it. This is a field that is moving very fast indeed. It is ideally suited to startups in some ways, although in the end you are going to need a big commercial infrastructure to cover the world.

—Mark Stevenson, president and COO, Life Technologies

Costs are still falling—and fast. Life Technologies has said it expected researchers to be able to scan a genome for less than $10,000 this year with its current system and thinks its second generation technology might eventually be able to reach the $1,000 mark. But it is within the so-called third-generation sequencing technologies that the most radical cost breakthroughs are expected.



Larry Kedes, senior advisor to the Archon X Prize, doesn't think any current commercial technology will be able to grab the $10 million bounty for sequencing 100 genomes in 10 days for $10,000 or less per genome. In fact, he hasn't seen any technology in development that he thinks can yet meet the stringent requirements of the prize.

Third-generation sequencing is not a single technology. Rather, it's a range of approaches being pursued by various companies. What they share in common is that they read DNA a single molecule at a time. Some argue that Complete Genomics technology in this regard is not really third generation but instead a souped-up version of second generation technology. They argue the company is using a massively parallel approach where cost efficiencies have come about in part through the company's ability to densely pack DNA into arrays and minimize the amount of reagents needed. But such distinctions will not be as meaningful as results. Complete Genomics calls its technology third-generation because of the efficiencies it says it has been able to achieve. "It will turn out one of our major costs will be electricity for running our data center," says Complete Genomics Reid. "The reagents cost is on its way to zero and the major cost will be electricity."

Among the technologies being looked at now is reading single DNA molecules in real-time as the enzyme polymerase is used to assemble a complimentary strand of DNA, mirroring the natural process of DNA replication that takes place within the cell. Fluorescent material bound to the different molecules that make up DNA, reveal the sequence. Pacific Biosciences, which calls its technology Single Molecule Real Time or SMRT, describes its approach as "eavesdropping" on a single DNA polymerase molecule as it assembles.

Unlike the truckloads of reagent needed for second-generation sequencing, this approach uses one molecule of reagent for each base pair, the same efficiency as inside the cell when DNA is replicated through natural processes. Life Technologies, through its acquisition of Houston-based VisiGen at the end of 2008, is pursuing similar technology.

Another approach is the so-called "nanopore" technology, which is being pursued by companies such as Oxford Nanopore Technologies, an Oxford, U.K.-based company backed in part with an $18-million investment from San Diego-based Illumina made this January. That technology also reads DNA a base pair at a time, but by pushing DNA through a tiny hole formed in protein. Other companies using the nanopore approach use synthetic instead of protein nanopores. An enzyme is used to cleave DNA one base pair at a time and the cleaved base pair is read as it passes through the nanopore.

But there are still other approaches being pursued. Some of the teams that have registered to compete for the Archon X Prize seem to have technologies that are unique. North Reading, Massachusetts-based ZS Genetics is using heavy elements to label DNA molecules and make them visible to modified transmission electron microscopes. Reveo, an Elmsford, New York-based company, is creating an electro-optic sequencer using what the company calls "nano-knife edge" probes to measure the frequency at which each base of DNA vibrates when excited by an electrical charge. It's a potentially rapid and inexpensive means of sequencing. Industry observers say it's likely that multiple technologies will emerge with strengths and weakness that make them well suited for one application but not another.

But it is not just a new generation of startups that are chasing low-cost sequencing. The big

players in the field today are also in the game. Companies such as Life Technologies, Illumina, Roche's 454 Life Sciences, and Helicos have been driving down the cost of their current technology and investing in next-generation technology.

The $1,000-genome will likely be available sometime in 2011 or 2012, predicts Mark Stevenson, president and COO of Carlsbad, California-based Life Technologies, the company formed in 2008 through the merger of Invitrogen and Applied Biosystems. The first to reach the goal will surely gain some recognition for hitting a milestone, he says. But he argues it will be more important to have a product that can be integrated into the entire biomedical ecosystem from research centers to electronic health records used by doctors. Some of the startups in the field may be successful at developing their technology, he adds. But it will take much more than that to be commercially successful.

"This is a young industry," Stevenson says. "We're just getting going. You are going to attract some smaller, newer players into it. This is a field that is moving very fast indeed. It is ideally suited to startups in some ways, although in the end you are going to need a big commercial infrastructure to cover the world. This is partly why Invtirogen and AB came together."

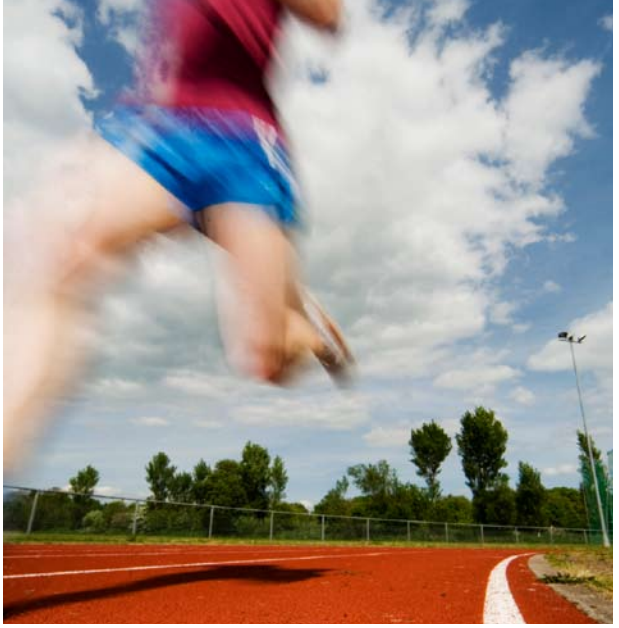
Larry Kedes, a senior advisor to the Archon X Prize for Genomics, the group offering a $10 million-bounty to the first group that can sequence 100 genomes in 10 days for $10,000 or less per genome is not surprised that no one has yet claimed the prize. In fact, he doesn't think any of the current commercial technologies are capable of winning. The professor emeritus of biochemistry and molecular biology at the University of Southern California also says he doesn't think the majority of the technologies in development that he's aware of will be able to meet the prize requirements for cost, speed, completeness, and accuracy.

The good news is, the marketplace initially may not require third-generation technologies to meet the X Prize goals. Some third-generation technologists and companies are going to be satisfied delivering less than the capability of the prize because they feel the market can tolerate that depending on the application of the sequencing and the improvements in cost and efficiency new technologies may offer initially. But ultimately, Kedes says what the X Prize is asking for is essentially what's needed for a medical payoff from sequencing. That, he says, is because there are lots of diseases and disease variants that are just not going to get picked up in less sophisticated scans unless you have that more granular, so to speak, information. The whole genome must not only be just sequenced—but done so with a high level of accuracy and completeness–to provide an understanding of genetic variation and what it means, he argues.

"There are a lot of very smart people out there with extraordinarily exciting technologies that have a theoretical shot at being able to do this," says Kedes. "I just don't think anyone has published anything yet or revealed anything yet that says they are even close to accomplishing the goals of the X Prize."

It is worth noting that when the runner Bannister did break the four-minute mile and set a new world record, it stood for a mere six weeks. On June 21, 1954, Australian John Landy bested Bannister's time by setting a new record of 3:57.9 at an international competition in Finland. Since then, it has become common for top runners to break the mark.

Though we have yet to see a commercial whole genome sequenced for $1,000, breaking that mark may well become routine in a few years. And while such a goal may have seemed beyond reach when scientists sequenced the first human genome, people are now talking about sequencing genomes for less than $100. It now seems likely that within a few years, whole genome sequencing will be affordable to most researchers who would want access to the technology. The question will be how quickly resulting discoveries gets translated into new understandings of disease and new treatments for patients. TJOLS



When Roger Bannister broke the four-minute mile, his astounding record stood for just six weeks and the mark is now routinely broken by world class runners.

Banking on the Future

Thanks to advances in scientific and computer technology, it's boom times for repositories containing human genetic material that can be analyzed to identify genetic variations associated with disease. After years of quietly collecting biospecimens, several biobanks are now conducting valuable research.

By Eric Wahlgren

CENTER FOR APPLIED GENOMICS AT CHILDREN'S HOSPITAL OF PHILADELPHIA

The genetic mystery of bipolar disorder is just the kind of case that genes detective Cathy Schaefer was destined to take on. The mental illness, characterized by severe mood swings, is a major one, affecting some 5.7 million Americans. And it's a psychiatric bulldozer, wrecking jobs, relationships, and quality of life. Anywhere between 10 percent to 20 percent of people with manic depression, as it's also known, commit suicide—and many more attempt it.

Mindful of the disorder's toll on society, Schaefer, a psychiatric epidemiologist, will lead the largest study to date of the potential factors that may put people at risk of developing it. Genes are a likely culprit. Children who have a parent or sibling with the illness are four to six times more likely to become bipolar, according to the National Institute of Mental Health. But identical twins—who share the same genes—don't necessarily both develop the disorder, suggesting environmental or other factors may also be to blame.

"The hope is that this will lead to the identification of new treatments and, to the extent that we're able, to the identification of environmental factors that may be more modifiable than genetic susceptibility," says Schaefer, director of the Research Program on Genes, Environment, and Health at the Oakland, California-based healthcare maintenance organization Kaiser Permanente. "We have some treatments for bipolar disorder, but they are medications that are difficult for many people to take and they certainly are not a cure."

As Schaefer and the other researchers begin the five-year study later this fall, they'll have at their disposal an unprecedented investigative tool: what's shaping up to be the biggest DNA repository in the United States. From Kaiser's "biobank," the investigators will be able to study DNA from 6,000 "controls," or people without the disorder. To discover any common genetic variants that may be associated with the illness, those will be compared to the DNA from 6,000 people of different ethnic backgrounds who have been treated for the illness.

While there have been previous genetic studies of bipolar disorder, they have involved smaller groups of people and have failed to determine for certain what genes predispose individuals to developing the illness. The biobank "makes it possible for us to do a study of sufficient size and sufficient power that we probably have an opportunity to really indentify particular genetic factors that may determine risk for the disorder," says Schaefer.

After several years in development, Kaiser's biobank began recruiting participants in 2007. The launch of the multi-ethnic study of bipolar disorder will mark its official opening for research business. The biobank passed a key milestone in August when more than 100,000 Kaiser members, all from Northern California, had sent in kits containing saliva, a rich source of DNA. Reaching the 100,000-level when it did, Kaiser says, means the biobank project is well on its way of having 500,000 of its members take part by 2013 (See Unique Assets, p. 40).

KAISER PERMANENTE RESEARCH PROGRAM ON GENES, ENVIRONMENT, AND HEALTH

We believe that this information, for the first time, will give us a good understanding of how genes, and which genes, interact with environmental factors to influence susceptibility to a wide variety of common diseases, but also influence the course of the disease and response to treatment.

—Cathy Schaefer, Director, Research Program on Genes, Environment, and Health at Kaiser Permanente

Cathy Schaefer, (*above*) executive director of the Kaiser Permanente Research Program on Genes, Environment, and Health, is seated on the left next to the program's Environmental Core Leader Stephen Van Den Eeden and Biorepository Core Leader Lisa Croen

A research associate at the Center for Applied Genomics (*opposite*) at Children's Hospital of Philadelphia inspects robotic equipment during the DNA labeling process..

Participating is painless enough. In addition to spitting into a container and mailing it back to Kaiser, members complete a five-page questionnaire on health, diet, lifestyle, and exercise. They also consent to having information from their medical record made available to genetic researchers. Down the road, the HMO may ask for individual blood samples, which also contain biomarkers related to diseases as well as information on environmental exposures, Schaefer says.

With all this data, researchers will seek to answer what Kaiser terms as some of the "biggest medical mysteries." Why does your brother get cancer, say, but you don't? Why does Prozac lift moods for some, but leaves others in the dumps? Does living near a freeway increase your chances of developing lung disease? Having the genetic samples from a half-million sick and healthy patients "will give us the range and statistical power to do the kinds of studies we want to do," says Diane Olberg, a spokeswoman for Kaiser's Research Program on Genes, Environment, and Health. The point, of course, is not only to solve these riddles, but also to come up with better ways to diagnose and treat cancer, mental disorders, asthma, diabetes, heart disease, and other conditions.

Guarding Biobanks

As the number of DNA repositories increase, society must contend with new security and ethical issues involving the protection of genetic information.

Just as biobanks may contain a gold mine of genetic information, these DNA repositories designed to reveal genetic variations associated with human diseases are taking Swiss bank-like precautions to keep the data safe. With Kaiser Permanente building what will possibly be the largest U.S. biobank with 500,000 participants, the Oakland, California-based health plan is something of a bellwether in the field.

Kaiser's security policy, which reflects those of other population-based biobanks, calls for labeling its volunteers' genetic samples and other health information with a code that is separate from members' health plan IDs. Access to that data is limited to only a small number staffers, who must have a special password. To fend off any potential hackers, Kaiser keeps the biorepository's computer databank locked in a secure facility and the system is defended by what it calls a state-of-the-art firewall. Kaiser declines to even disclose the facility's location, saying only it's somewhere in Northern California.

Still, Kaiser, following common practice in its biobank consent forms, states there are risks. A privacy breach is one. Another is the chance that biobank research may lead to a discovery that a person's genes may put them at risk for developing a certain condition, causing others to treat them differently if they find out about the connection. Some peace of mind about potential discrimination, however, may come from the Genetic Information Nondiscrimination Act of 2008. GINA, as it's known, makes it illegal for health plans or insurers to deny coverage of a healthy person because genetic information suggests predisposition to a disease. It also prevents employers from using any genetic information in hiring, firing, or other job-related decisions.

Where things get a little fuzzier in the biobanking world is deciding how to make sure that any individual who participates in a genes research project does so with "informed consent." In other words, are participants fully aware of how their genetic and health information will be used? And are they agreeing to be exposed to any research risks voluntarily? Biobanks, including Kaiser's, have institutional review boards made up of independent experts who establish ethics guidelines and approve any study before they begin. But the United States has no comprehensive regulatory framework to determine what is the best way to obtain informed consent, says bioethicist Karen Maschke, a research scholar at The Hastings Center, a nonprofit bioethics research institute in Garrison, New York.

Some institutions ask participants for "tailored" consent, or what is essentially approval from the individual to use biospecimens for specific types of research, such as only for diabetes studies. More typical of the larger biobanks, Kaiser informs participants that genetic material and other information could

Kaisers' researchers have their work cut out for them. The DNA samples, now stored in a secure facility in a Northern California location (Kaiser declines to disclose exactly where for privacy reasons) will be separated into smaller amounts and analyzed to obtain information about genes (See Guarding Biobanks, p. 36). That information will then be used along with the data collected in the self-reported health surveys, as well as in Kaiser's electronic health record system, to identify patterns of disease. The researchers will also tap into databases containing data on air pollution, water quality, proximity to parks, and other environmental factors to incorporate how a person's environment can influence the development of all sorts of health conditions. "We believe that this information, for the first time, will give us a good understanding of how genes, and which genes, interact with environmental factors to influence susceptibility to a wide variety of common diseases, but also influence the course of the disease and response to treatment," Schaefer says.

Biobank research and any resulting therapies may not benefit an individual biobank participant for a very long time, if ever. The donor is not paid for supplying DNA and doesn't stand to profit if their biospecimens are used in research be used in a variety of different studies. "Since this is a new area of science that changes quickly, we don't know now which genes scientists will study," its consent form says. The health plan says its institutional review board, which is responsible for protecting the rights and welfare of participants, will have to approve any study. "The argument has been made that with this type of consent, to respect autonomy you have to give people the option to participate as long as you tell them what it is for and that you have review safeguards," says Maschke, who is also editor of *IRB: Ethics and Human Research*.

But she says, "there remains disagreement on what is the right way to gain consent." This fall, the Paris-based Organization for Economic Co-operation and Development, which is made up of 30 countries including the United States, is expected to release proposed common standards on how biorepositories should collect material, a move that could ultimately influence legislation on the subject.

The field gets trickier still when it comes to figuring out who has ownership rights to any inventions, including diagnostic tests or pharmaceutical products that may result from biobank research. Released in 2007, the National Cancer Institute's best practices for the field call for investigators and institutions to share the research and tools created through the use of biospecimens, Maschke says. Typically, she says, biospecimen donors don't have any rights to intellectual property. "The understanding is they want drugs to be developed to get us better," she says.

For its part, Kaiser says none of its participants or employees will receive any personal financial benefit from any kind of commercialization effort. Any royalties will be used for research and non-profit public benefit purposes, Kaiser says. "Kaiser is not building this as a profit center," says Diane Olberg, a Kaiser genes research project spokesperson.

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As the field grows, however, it's likely that ethical and ownership debates will heat up. What happens, for instance, if down the road a participant can't afford a new drug or treatment that was developed by a pharmaceutical company from research conducted using that person's biospecimen, among others? "If I can't, as a person who helped you get access to a drug or test, pay for that drug or test, is that okay?" asks Maschke. Most biobanks have data access committees, Maschke says, which set up guidelines for who gets access to the research and genetic data, but these guidelines are "not so clear-cut." Indeed, it sounds like biobanking won't just keep genetic researchers awfully busy, but bioethicists and lawyers, too.

—E.W.

PUBLIC POPULATION PROJECT IN GENOMICS

Right now, we are seeing a boom. People in various countries are saying that, as part of their healthcare strategies, they need to have biobanks that can be used for research of very high quality to determine the genetic and environmental interactions responsible for complex diseases.

—Mylène Deschênes, Executive Director, Public Population Project in Genomics

As executive director of the biobank consortium Public Population Project in Genomics, Mylène Deschênes is encouraging biorepositories to develop universal standards so that reserachers can get access to larger pools of genetic data as well as more easily replicated findings.

that leads to a new therapeutic. "The argument is you give your consent to have your biospecimens used in research knowing that it is important to society that somebody develop a diagnostic or drug intervention that works," says bioethicist Karen Maschke, a research scholar at The Hastings Center, a non-profit bioethics research institute in Garrison, New York.

Kaiser is hardly the only population-based biobank, a term used to characterize projects such as the HMO's that seek to identify genes that contribute to disease using repositories of donated human DNA from large numbers (anywhere from 20,000 to 1 million) of volunteers with and without disease. There are at least 137 large population-based biobanks in some 40 countries, according to Isabel Fortier, research director at the Public Population Project in Genomics, or P3G, a Montreal-based international biobank consortium. There are likely hundreds more, smaller "tissue banks," another type of biobank typically focused on a particular disease. A tumor bank, for instance, would look at tumor specimens from cancer patients to identify biomarkers associated with cancer.

In the United States, Northwestern University and the Mayo Clinic are among some of the many major institutions in various stages of developing biorepositories. With Canada, Estonia, Singapore, and Sweden among the other countries with population-based biobanks in the works, the field is taking off around the globe. "Right now, we are seeing a boom," says Mylène Deschênes, P3G's executive director. "People in various countries are saying that, as part of their healthcare strategies, they need to have biobanks that can be used for research of very high quality to determine the genetic and environmental interactions responsible for complex diseases."

With the growth of biobanks—China has plans to build the world's largest gene bank about 165 miles northwest of Shanghai—key to tapping their full potential will be making them compatible with each other, experts say. The U.K. Biobank is one of the largest and most ambitious projects to date, having enrolled more than 300,000 Britons since it launched in 2007. That puts it ahead of schedule of reaching its 500,000th person by mid-2010. But if Kaiser researchers in the future, let's say, want to use genetics data available from the U.K. Biobank, there must be common tools and methods to harmonize the data across nations, says P3G's Deschênes. That's part of the reason the U.K. Biobank and Kaiser's biobank are both charter members of P3G.

One of P3G's main goals is to come up with universal biobank standards, a move that would boost researchers' ability to replicate findings—a requirement in scientific research. The European Union has launched a separate initiative to develop guidelines to improve coordination among the Continent's growing number of biorepositories. "Some research is not possible unless you can get access to a large pool of data," says Deschênes. "One of the analogies that is often used is the track and the train. You have different trains if you want, but at least you can have similar tracks you can run on."

There are several reasons for the building spree. For starters, recent advances in technology have made the research possible. The sequencing of the human genome in 2003 cracked the human genetic code by determining the exact order of the chemical base pairs that make up DNA, the chemical compound that contains the genetic instructions needed to develop and direct the activities of every organism. Ever-more powerful computers allow researchers to swiftly scan markers across the complete DNA sets, or genomes, of many people to find genetic variations associated with a particular disease. This approach is called a genome-wide association study.

What's more, the cost of using the technology continues to fall. Companies today are racing to be first to sequence the human genome for $1,000 or less. Only six years ago, an estimated $500 million was spent on sequencing the first human genome (See "Speed Freaks" p. 28). "The technology just wasn't there until three or four years ago in order to do this in an effective way," says Hakon Hakonarson, the director of the Center for Applied Genomics at Children's Hospital of Philadelphia, which is building a biobank with 100,000 samples to be able to determine which genes are responsible for certain pediatric conditions. The center has gathered blood samples from 50,000 children since it launched in 2006 and it's still collecting several hundred samples every week, Hakonarson adds. When it's done, it will be the world's largest biobank dedicated to genetic analysis of childhood diseases.

One reason that interest in biobanks is heating up is that after several years of rather quietly building their systems and biospecimen deposits, repositories are beginning to produce research. Since it launched three years ago, Hakonarson's biobank has been in overdrive, having already helped identify gene variants that increase a child's risk to Crohn's disease, type 1 diabetes, and neuroblastoma, among other discoveries. The research, Hakonarson predicts, could eventually lead to more effective, targeted treatments. "I think you are going to see a shift in treatments," says Hakonarson, a native of Iceland, where he worked as chief scientific officer at DeCODE Genetics, the company that helped the island nation pioneer biobanking in 1997. "Existing drugs are not directed at treating the cause of the disease. You treat blood pressure by dilating the vessels or increasing the excretion of the kidneys. But when we know what causes the disease, we can come in and basically correct the problem."

Kaiser's Schaefer says the type of genetic research made possible through population-based biobanks could also lead to breakthroughs in pharmacogenetics, or the understanding of how genetic variations account for different responses in drugs. Problem is, some drugs work better in some people than others. Consider that some 38 percent of people on average don't respond to a particular class of anti-depressants and that percentage of ineffectiveness can jump to 75 percent for certain cancer drugs, according to the Personalized

KAISER PERMANENTE RESEARCH PROGRAM ON GENES, ENVIRONMENT, AND HEALTH

Medicine Coalition. "With a better understanding of how genes influence response to medication, you'd be in a better position to better prescribe the best medication for someone," says Schaefer.

Kaiser's biobank will begin to be put to the test later this fall with the launch of the bipolar study, to be conducted jointly with the University of California, San Francisco's Institute for Human Genetics. Schaefer is optimistic that the study, funded with a $12.7-million grant from the National Institute of Mental Health, will help lead to better treatments. Mood stabililizers, anti-depressants, and atypical antipsychotics all are used to treat bipolar disorder, with varying degrees of success. But they usually have side-effects. "One of the fascinating things about the better understanding of how genes operate in a disorder like bipolar disorder is they can actually suggest new physiologic

Karen Silva, a research staff member with the Kaiser Permanente Research Program on Genes, Environment, and Health, holds a saliva collection kit.

pathways that are affected by the disease," says Schaefer. "By knowing these pathways, you can develop entirely new medications, for example, that target those pathways."

Meantime, Kaiser researcher Stephen Van Den Eeden has received $2.3 million in grant money from the National Cancer Institute for a joint study with UCSF of prostate cancer in African-American men to begin in the fall. Over a five-year period, the researchers will study 1,500 African-American men with prostate cancer and 1,500 controls, in part to shed light on some troubling statistics: African-American men are 61 percent more likely to develop prostate cancer than whites.

At Children's Hospital of Philadelphia, Hakonarson hasn't wasted any time since joining the institution's $40-million Center for Applied Genomics in 2006. Some of the most promising work so far has been done with neuroblastama, a cancer that first appears in the developing nerves of a child, often as a tumor in the chest or abdomen. Led by John Maris, director of the hospital's Center for Childhood Cancer Research, the institution used genome-wide scans done at Hakonarson's biobank to analyze DNA from families with a history of the often fatal disease. The researchers discovered gene mutations—in the anaplastic lymphoma kinase or ALK gene—that are the main cause of the inherited form of the cancer.

The discovery, the hospital says, paved the way for the simple screening of patients with a family history of the disease. Now a urine test or ultrasound can help monitor children for signs of the cancer. And, as it happened, several pharmaceutical companies at the time were already developing ALK inhibitors in the lab. Previously, researchers had discovered that ALK mutations raise the risk for lymphoma and lung cancer in adult patients. The upside? The drug that Pfizer was developing to treat these

Unique Assets

Kaiser Permanente's biobank leverages patient diversity, environmental data, and electronic health records.

Started in 2005, Kaiser's biobanking project began enrolling participants selected at random from its Northern California region's 3 million members two years ago. The startup money included an $8.6-million grant from the Robert Wood Johnson Foundation, the biggest philanthropy in the United States to be focused exclusively on healthcare issues.

Kaiser says its biobank, which expects to have 500,000 samples from its members by 2013, will be unique for several reasons. Among them is the diversity of its subject population. With researchers interested in discovering any possible ethnic susceptibility to disease, it cites the fact that California has the largest minority representation of any U.S. state, making up 57 percent of the population.

Another asset: The state—and particularly the northern region—has some of the most complete data in the world on air pollution, pesticide use, and traffic density. The same goes for statistics on the so-called "built-in" environment, such as available food outlets, green space, bicycle paths, and senior centers, Kaiser says. With the availability to correlate the information to places where a Kaiser member has lived, the researchers believe they may get closer to understanding the outcomes of various health behaviors and environmental exposures on a neighborhood level.

"You can see what the overlap is between different kinds of exposures, where they occur, and develop different ways to relate that to individual members' residential histories so that you know who has actually been exposed to what and at what level," says Cathy Schaefer, director of Kaiser Permanente's Research Program on Genes, Environment, and Health.

Kaiser will also be able to lean on its electronic health record system KP HealthConnect, considered the world's largest privately funded computerized medical records network. Across the United States, it serves the HMO's 8.7 million members. As an example of its usefulness, Kaiser was able to study the medical data for 1.39 million of its members to find that high doses of the painkiller Vioxx tripled the risk of heart attacks. The Merck drug was pulled from the market in 2004. "The finding that Vioxx was associated with an increased risk of heart disease shows you the power of assembling information on a very large group of people," Schaefer says.

—E.W.

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their biospecimens for research, according to a recent survey by the Johns Hopkins University Genetics and Public Policy Center.

But as public participation becomes more common, it's likely that ethical issues will arise. For instance, what happens if research reveals a particular participant has a genetic predisposition to a serious disease when biobanks are focused on producing generalized research? For its part, Kaiser commits to re-contacting members about whether they want to learn the results if they find something they believe "is of substantial medical importance." But The Hastings Center's Maschke says different biobanks may end up taking another tack. "Whether people are going to actually provide specific results has yet to be worked out," says Maschke, who is also editor of *IRB: Ethics and Human Research.*

In addition to potentially tricky ethical issues, there are more basic challenges. Biospecimens can degrade. And, patients can leave health plans like Kaiser or Children's Hospital of Philadelphia, potentially depriving researchers of the longitudinal data they may need to understand disease progression. What's more, a greater knowledge of complex diseases—or diseases involving multiple mutations—such as cancer and diabetes could lead to the conclusion that any fixes are equally complex. "It is a little bit irreducible," says Schaefer.

I think you are going to see a shift in treatments. Existing drugs are not directed at treating the cause of the disease. You treat blood pressure by dilating the vessels or increasing the excretion of the kidneys. But when we know what causes the disease, we can come in and basically correct the problem.

—Hakon Hakonarson, Director, Center for Applied Genomics at the Children's Hospital of Philadelphia

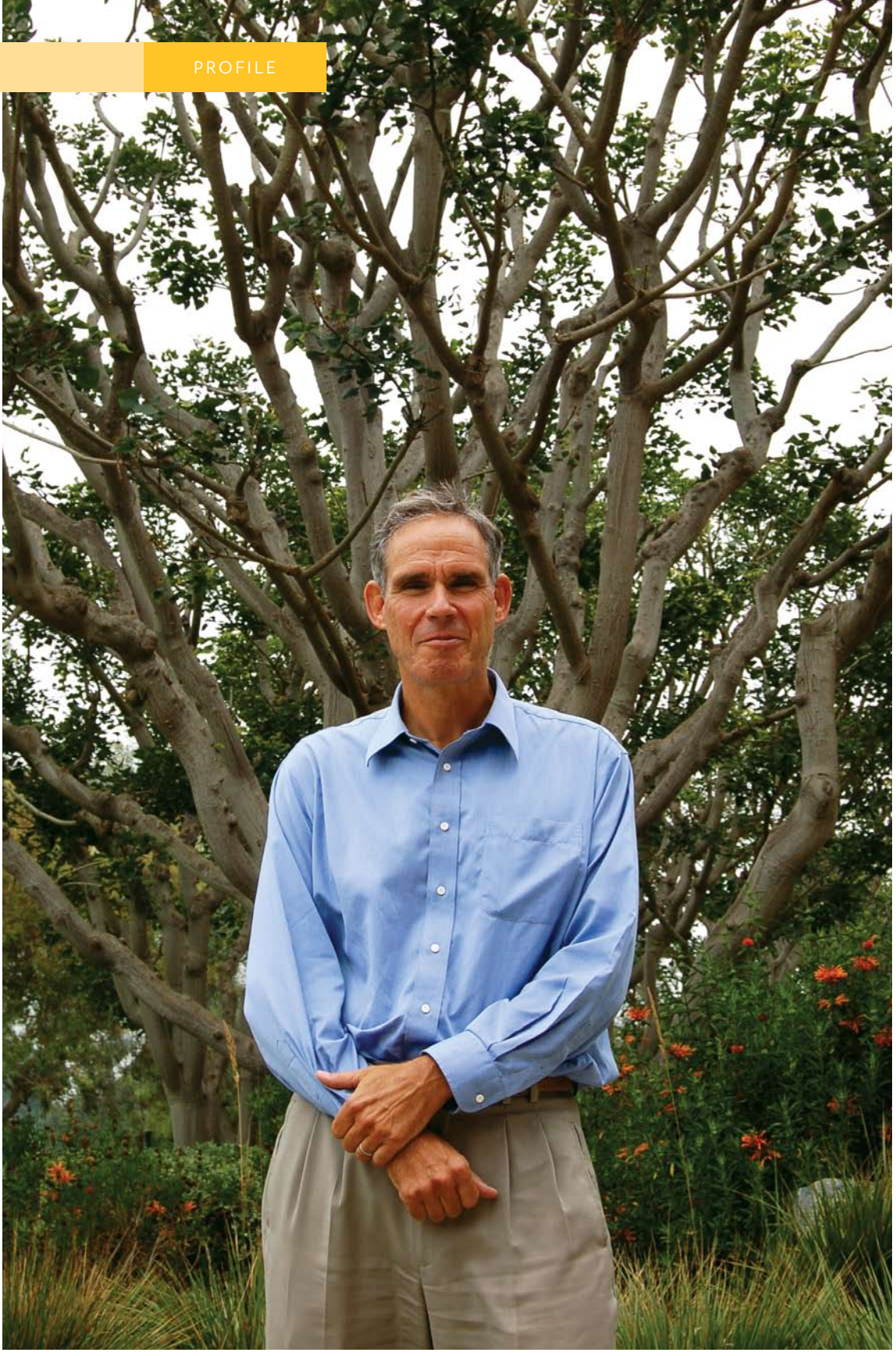
other cancers is now in clinical trials for pediatric patients, Hakonarson says. "Now we were able to partner with the pharmaceutical company and get access to their medication and start treating these patients," says Hakonarson, a pediatric pulmonologist by training.

Another recent study at the hospital using genome-wide association technology identified a gene variant that raises a child's risk of Crohn's disease, a chronic inflammatory condition of the gastrointestinal tract. A separate study discovered a gene variant that raises a child's risk for type 1 diabetes, an autoimmune disorder in which the immune system destroys insulin-producing cells in the pancreas. "We are gradually translating these findings so that we can fully understand where we should intervene and how," Hakonarson says. "You need to know actually what the gene does in order to interfere with the process."

With the promise of better understanding of disease, and ultimately better treatments, biobanking has broad public support, despite the novelty of the field. Some 60 percent of Americans say they would be willing to donate

But if all goes as planned, Kaiser says its doctors may some day be able to make healthcare plans based on their patients' genetic profiles and life experiences, helping to speed the adoption of more personalized medicine. Better yet, research from the biobank could actually lead to better ways to prevent disease, Schaefer adds. "In order to have really good strategies for prevention, which is really what you'd like to do is prevent health problems, you have to know what it is that causes various health problems to occur." If biobank research eventually teaches us how to stop disease from developing in the first place, would Kaiser and other health plans eventually run themselves out of business? If that's ever the case, it's a long way off. TJOLS

Hakon Hakonarson, director of the Center for Applied Genomics at the Children's Hospital of Philadelphia, is a native of Iceland, where he worked as chief scientific officer of DeCODE Genetics, the company that helped the island nation become a leader in biobanking.



DANIEL S. LEVINE

Lost in Translation

Eric Topol doesn't just want to understand the genes that drive illness and wellness, he wants to make sure that such knowledge actually changes the way doctors practice medicine.

By Daniel S. Levine

Shortly after arriving in La Jolla, California nearly three years ago, Eric Topol found himself addressing a room full of San Diego's business leaders at the exclusive University Club with its grand views of the city below. The former top cardiologist at Cleveland Clinic had just recently come to town to become director of the Translational Science Institute at the Scripps Research Institute, the world's largest independent non-profit biomedical research facility. Topol, who was speaking about the future of medicine, told the crowd at the end of his talk in March 2007, "You folks are known for wireless and you are known for tourism. But in the future you are going to be known for the future of medicine, for genomics, and individualized medicine."

If Topol succeeds in his efforts to lead broad genomics studies at Scripps—that talk won't be the last time that San Diego's business elite hear about individualized medicine. The term refers to whole medical approach that incorporates the knowledge of a particular individual's genetics to deliver appropriate care. "It's about being able to understand what makes a person either susceptible, or protected, or responsive, or unresponsive to various treatments, devices, drugs, or whatever," says Topol, who at 55 has the fit appearance you'd expect in a cardiologist (at least one you'd trust). Topol, however, bristles at the mention of "personalized medicine," the more commonly used term for this new field, saying it confuses patients. "It sounds like a concierge, the person who takes you around the hospital and makes sure you have coffee and know where the restrooms are," he says. Individualized medicine is "not about treating someone as a VIP."

It wasn't surprising that weeks after landing in San Diego, Topol would declare that the city's future lies in individualized medicine. After all, he was leading an effort in translating an understanding of human genetics into better medicine. But it was not an idle boast. Since he first settled in at the Scripps Institute in January 2007, Topol has been doing everything in his power to make it so. As a high-profile researcher and clinician, his goal is not just to find genes that can make medicine more predictive, preventive, and, individualized. He wants also to make sure these findings get tested in the clinic and put into practice.

> The future of medicine is going to be integrating genomic science into the clinical treatment of individuals and there are not very many physicians who are equipped today to perform that or to bring genomics into the clinic. In that sense, Eric is already a global leader.
>
> *—David Gollaher, President and CEO, California Healthcare Institute*

"The future of medicine is going to be integrating genomic science into the clinical treatment of individuals and there are not very many physicians who are equipped today to perform that or to bring genomics into the clinic," says David Gollaher, president and CEO of the California Healthcare Institute, a La Jolla, California-based biopharmaceutical industry advocacy group. "In that sense, Eric is already a global leader. There's no question about it. That's the mission he's taken up. He's the prophet of genomics and genomic science."

Eric Topol, director of the Scripps Translational Science Institute, is branching out beyond genomics to include wireless healthcare technology in his work in the hopes of translating findings about genes into improved care for patients

DANIEL S. LEVINE

This is something that's very near and dear to him. Can we leverage genetics and genomics? That's one question—can we design drugs or trials that target people with certain genetic profiles. The other one is to maybe leverage wireless technologies.

—Nicholas Schork, Director of Research, Scripps Genomic Medicine Program

Topol examines a map of the United States that tracks patients in the Wellderly Study. His daughter Sarah Topol (*right*), a registered nurse, heads up recruitment of participants for the groundbreaking look at the genes of healthy people older than 80 who have never suffered from chronic diseases.

Gollaher notes there is always a big lag between basic scientific discoveries and their application in the clinic. He points to the 19th-century discoveries of Robert Koch and Louis Pasteur and the germ theory of disease, which took more than a generation to be incorporated into clinical medicine in the form of antiseptics. "There will be a lag," he says, "and it will be people like Eric who compress that and make it available earlier rather than later."

Though Topol's office sits along the fabled Torrey Pines Golf Course, he says he doesn't get to play often enough to be any good. It's no wonder. Since arriving in La Jolla, he's been quite busy. Among the accomplishments he can already check off on his list: He's brought together basic science researchers and clinicians from the disparate arms of Scripps to launch the Scripps Translational Science Institute. He led the institute's successful effort to land a $20-million grant from the National Institutes of Health under its Clinical and Translational Science Awards program—the only non-university to date to win such an award. He's also attracted $45 million in funding from the Gary and Mary West Foundation to launch the West Wireless Health Institute. The organization is set to conduct clinical research on the use of wireless sensors to prevent, monitor, and manage disease in patients. And, he's mapped out plans for a medical school at Scripps with a focus on translational medicine. But that project for now is stalled over resolving the issue of a $100-million naming grant.

Were all that not enough, he's been earning style points, too. In 2008, he was one of 10 medical researchers named a "Rock Star of Science." The distinction resulted in Topol being featured in a *GQ* magazine photo spread wearing designer garb alongside Sheryl Crow, Seal, Will.i.am, Joe Perry, and Josh Groban. It was part of a campaign by designer Geoffrey Beene called "Geoffrey Beene Gives Back" to call attention to the contributions of medical researchers and the need to accelerate the translation of discoveries into cures. "I never have enough to do," says Topol. "I require a lot of stimulation or I get bored."

Boredom shouldn't be a problem for Topol at the Scripps Translational Science Institute.

Already, the genomics projects are stacking up. Among the most compelling is the "Wellderly Study," an examination of the DNA of people 80 and older who have had no history of chronic disease. The goal is to unlock the genetic secrets to longevity. Topol says to date, medical research has largely centered on finding genetic markers for disease. This focus on sickness has neglected the genetics of health.

Already, 750 people have enrolled in the study. Though the results are preliminary, the findings so far are surprising. The wellderly appear to have the same bad genes—those that have been linked to such illnesses as Alzheimer's, heart disease, and cancer—as everyone else. However, there is an early indication that they may also have modifier genes that are unique to them. These genes appear to mediate the expression of the disease-linked genes.

Another major study underway is an effort to find out the behavioral impact of personal genetic testing on people who want to learn their potential risk for developing certain diseases. About 5,000 participants have enrolled in the Scripps Genomic Health Initiative as it's called. The study is a joint effort between Scripps, software giant Microsoft, consumer genetics company Navigenics, and genetic analysis tools maker Affymetrix. The study will follow participants for as many as 20 years to see what the near-term and long-term changes they make in their behavior, lifestyle, and the medical care they seek.

Though just begun, the study is already having an effect, Topol says. One participant, a relative of Topol's who had resisted getting a colonoscopy, decided to have the diagnostic procedure after she learned she had a three-times greater than normal risk for developing colon cancer. In another instance, one colleague learned he had a six-fold elevated risk for psoriasis, a chronic condition characterized by red, scaly patches of skin. In fact, the testing helped him discover he had already been walking around with the condition on his leg for 10 years.

Other studies at the institute examine genetics to better tailor drug therapies to patients. One such study involves using a simple saliva genotyping on patients before prescribing the blood-thinner Plavix. The drug is commonly used to prevent heart attack and stroke in patients at risk for developing blood clots. Plavix relies on the metabolic action of the body to convert the drug into its active form, but patients with a common genetic variant are unable to do so. In fact, 50 percent of Asians and 40 percent of African Americans cannot properly metabolize the drug. The study is being run in conjunction with all of the Scripps medical facilities, giving researchers access to data from a broad patient cross-section. "They're taking a drug for $4 a day for the rest of their lives or whatever, and it doesn't work," says Topol, who notes there are other therapies available for such patients. "It's an exciting project because using this test could become the norm some day."

Topol's interest in genetics started long before his medical career. Born in Queens, New York and raised in the Long Island suburb of Oceanside, Topol was bored with high school, having skipped two grades. At just 15, he entered the University of Virginia in Charlottesville. As a college student in 1975 he wrote his thesis on "The Prospects for Genetic Therapy in Man."

He supported himself in college by working the night shift at the UVA hospital. He had planned to become a biomedical engineer, but that changed when he saw patients in the intensive care unit. Patients who looked as if they were going to die eventually transformed and became well again. "I said, 'This medical stuff is pretty impressive,'" he recalls. "Of course I was seeing the rare bird—the person that was actually helped—because most people in the intensive care unit don't necessarily do so well. But it colored my thinking about how medicine could take people who were critically ill and get them in a much better state."

Topol went on to study medicine at the University of Rochester. There, in his third year, he met his wife Susan, a nurse at the time. His housemates told him to invite some nurses to a party they were throwing. He was in the midst of an obstetrics rotation. He wanted to invite Susan, but he didn't know how to overcome his shyness. His solution was to invite all of the nurses in the department, most of whom were over 50. The ruse worked. Within two weeks, he and Susan were engaged. After 31 years, they're still married and have two grown children.

Growing up, Topol had a close view of the toll of chronic disease. His father had developed type 1 diabetes as a teenager and suffered many of the ill-effects from it later in life, including losing his sight. Though Topol thought he might eventually focus on endocrinology, he became interested in cardiology while doing an externship. He started in the intensive care unit at the University of California, San Francisco in 1979. There, he became influenced by the cardiologist Kanu Chatterjee, whom he calls one of his mentors. It was an unusual time in cardiology as

there were new breakthroughs in the treatment of heart patients. Among them was the injection of streptokinase into the coronary arteries of heart attack patients to dissolve clots. There was also the use of new technologies, such as balloon angioplasty.

"That timing, and having a great mentor at UCSF, really captivated me," says Topol. "It was Chatterjee and that era. It was just so exciting. You could hardly not feel the palpable excitement of the field at that time."

Shortly before moving on to a fellowship at Johns Hopkins University, he read a study about a new treatment being developed to dissolve clots called tissue plasminogen activator or tPA. The journal article examined the use of tPA to dissolve vein clots in dogs. He discussed tPA with a colleague, who pointed him to a young biotech company with a handful of employees at the time called Genentech. The company was thinking of developing tPA to treat phlebitis, a condition associated with deep vein blood clots. When Topol contacted Genentech, he told them it would be great to try using it to treat heart attack patients. He met with Bob Swift, the director of research at the time, who suggested he join the company to lead the clinical effort on tPA. Topol explained he couldn't because he was about to begin a fellowship at Johns Hopkins. So Swift suggested Topol be the first to give tPA to heart attack patients.

Genomics only tells about biology. In any given person all I can say is they have a predisposition to atrial fibrillation or sleep disorders, or this or that. With physiology—the elegant phenotyping we've never been able to do before—we can have an entire ICU in someone's home monitoring all of their vital signs. It gives us a different look at a patient. It gives us their continuous physiology.

—Eric Topol, Director, Scripps Translational Science Institute

Once at Hopkins in Baltimore, Topol immediately went to the chief of cardiology and told him about the unique opportunity. The hospital could be the first to put this new clot-busting biotechnology product in patients. "At first he thought, 'this guy is freakin' crazy,'" recalls Topol. "'What did I do accepting him in our fellowship program?'" But after a few days—and the realization that the study of the treatment could attract grant money—the chief grew interested, he says. Topol began by studying tPA in rabbits with atherosclerotic clots. Eventually, in 1984, he did deliver the first dose to a patient. He remembers the moment in great detail.

"People were cheering and jumping up and down and crying that we had actually opened up the artery," he says. "It was one of the most striking moments of my life. February 11, 1984 at around 2:30 in the afternoon. It still plays back as one of those monumental moments. It definitely had a big impact on me and my subsequent career." In retrospect, Topol says the dose was too low to work. But he believes that the process of repeatedly injecting dye into the patient with a catheter for imaging probably broke apart the clot. Nevertheless, the event drew national headlines.

Topol continued working on tPA at the University of Michigan. There, he became a professor and met his goal of being tenured by the age of 35. He spent six and a half years there, eventually serving as both a professor of internal medicine and director of the catheter lab and director of intervention. At Michigan, Topol started a series of major, multi-center clinical trials including the TAMI trial and later the GUSTO trial—both major tirals of tPA in heart attack patients. At the time, GUSTO was the largest randomized trial of any kind initiated in the United States with 41,000 patients. A third trial—EPIC—looked at the use of the monoclonal antibody ReoPro to prevent clots in patients undergoing angioplasty.

Topol left Michigan for the Cleveland Clinic in 1991, bringing all three trials with him. While there, he raised Cleveland Clinic's profile in cardiology, building it into the country's leading cardiology program from its ranking as fourth.

Despite the clinical successes, by the early 1990s Topol had grown troubled that heart attack therapy had "hit the wall." Patients, when he looked at data from the late 1980s forward, were still dying at the same rate. Despite improvements in treatment, patients weren't coming into the hospital any earlier—about two and a half hours on average after suffering a heart attack. And by the time a doctor dissolved a clot, much of the damage was already done. "Even though it did save lives, nothing was really taking it to the next level," says Topol. "I started thinking there is only one way we are

Practicing What He Preaches

Though he is conducting cutting-edge research in genomics, translational medicine, and wireless healthcare technology, Eric Topol still practices medicine with an approach that's informed by his interest in prevention and wellness.

With a long list of titles and a full spate of research projects, it's easy to forget that Eric Topol continues to practice cardiology. Among the people who haven't forgotten, of course, are his patients like telemarketing tycoon Gary West. West's doctor-patient relationship was a tad unusual in that it helped give shape to the West Wireless Health Institute, a first of its kind research institute to focus on the use of wireless technologies to improve human health. But at the end of the day, Topol has also been his cardiologist, providing West with an up-close and personal view of Topol the doctor.

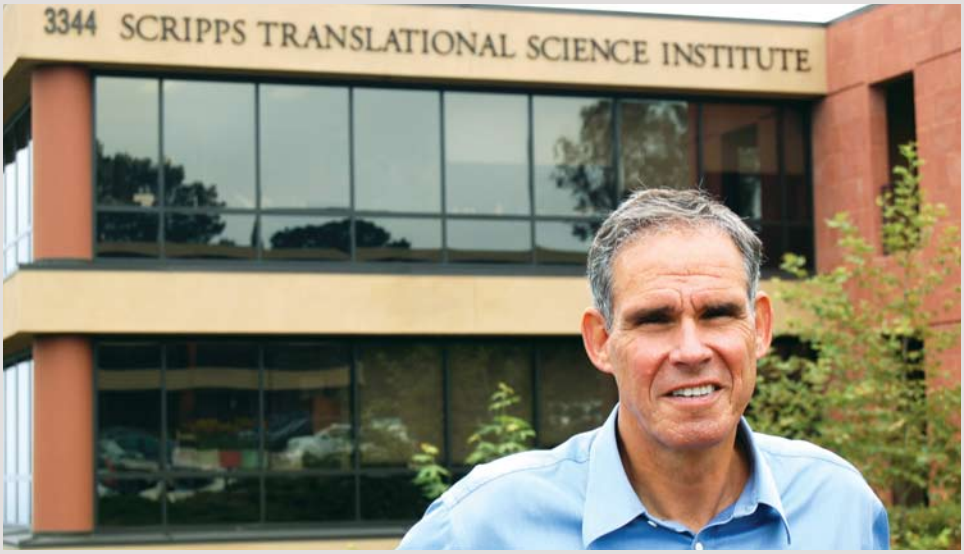
The connection began in 2007 when West, the founder and chairman of the West Wireless Health Institute, had been looking for a cardiologist. A friend suggested he try Topol. The two hit it off and West invited Topol to lunch. Over the course of the meal, West discovered they shared a mutual interest in wireless medicine and the potential it offered to cut healthcare cost and transform the field. The thinking is that by monitoring patients as they go about their everyday lives with wireless devices, doctors can detect problems early before they become expensive to treat.

West says Topol, who now serves as chief medical officer for the West Wireless Health Institute, among other responsibilities, is also focused on prevention in his clinical practice. "In the past, I went in, had a stress test and an echo—the normal things cardiologist do every couple of years. They'd say 'you're doing great, have a good day,' and didn't mention I was 30 pounds overweight. I'm like anybody else—that was good news to me," says West. "Eric took a different approach."

Even though Topol is younger than West, West says Topol sat him down in a fatherly manner. He told him that while his test results could be fine, sooner or later his bad habits would catch up to him. One day, his stress test results wouldn't be as good as he would like them to be, West recalls Topol telling him. "He's the only cardiologist who has had success in getting me to do what I'm doing now," says West. He credits Topol with persuading him to lose weight, adhere to an exercise plan, and change his eating habits including giving up red meat.

"Eric is a big wellness and prevention guy," says West. "He just flat out believes the stuff and he's right about it. That's the same thing we have to carry over into our whole medical system."

—D.S.L



DANIEL S. LEVINE

Eric Topol At-A-Glance

Current Appointments

- Director, Scripps Translational Science Institute
- Professor of translational genomics, department of molecular and experimental medicine, The Scripps Research Institute
- Chief Academic Officer, Scripps Health
- Chief Medical Officer The West Wireless Health Institute

Education

- University of Virginia, BA
- University of Rochester, MD
- University of California, San Francisco Internal Medicine Residency
- Johns Hopkins Fellowship in Cardiology
- University of Michigan, Tenured Professor
- Cleveland Clinic, Provost and Chief Academic Officer
- Founder of the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University

Awards & Activities

- Elected to Institute of Medicine, National Academy of Sciences, 2004
- Simon Dack Award, American College of Cardiology
- Andreas Gruntzig Award, European Society of Cardiology
- Johns Hopkins Society of Scholars
- American Association of Physicians
- American Society of Clinical Investigation
- American Heart Association Top 10 Advance (2000,2004)

going to get this thing better, and it is by preventing the event in the first place."

It was then that Topol started the very first cardiovascular gene bank at Cleveland Clinic. To study the genetics of heart attack, he won an $18-million, five-year NIH grant. The effort began in 1995 and was built out within three years to 10,000 patients. Part of the project included collecting DNA from 400 families in which parents and siblings suffered heart attacks. The study concluded with major findings, including one that linked heart attacks to people that had a rare gene deletion and the other involved the discovery of a genetic variant that puts people at elevated risk for heart attack. The study won recognition from the American Heart Association, which honored the work with a Top 10 Advance award in 2000 and 2004.

It was while at Cleveland Clinic as chairman of the cardiovascular medicine department that Topol wrote what was to become the most oft-cited paper of his career. Published in the *Journal of the American Medical Association*, the paper was the first to document that use of painkiller Vioxx, a drug being used by 20 million people, carried an elevated risk of heart attack and stroke. "It kind of took over my life in 2004," he says. "It wasn't pleasant in 2001 when I published the paper because Merck sent all sorts of people to go after me, whether it was in the press or in other ways. But then in 2004, when they withdrew the drug, it got much uglier. It was the most unpleasant time in my career."

Topol, who remained a vocal critic of Merck, found himself under attack both professionally and personally. Press reports at the time say Merck sent letters to doctors across the country seeking to discredit Topol. He found himself the subject of an article in *Fortune* about conflicts of interest because he served on the medical advisory board of a hedge fund that had shorted Merck's stock. He and his family received threatening phone calls late at night warning him to stop talking about Vioxx and Merck. Press accounts at the time quoted him as saying that then-Merck CEO Ray Gilmartin took his complaints to Cleveland Clinic chairman of the board of trustees Malachi Mixon, whom he knew personally. Cleveland Clinic never confirmed or denied such conversations took place, but Topol was removed in 2005 as head of the clinic's medical college. Topol declined to discuss details of what happened at the Cleveland Clinic, saying only that he left voluntarily.

It was not the first time that Topol's research may have angered the medical establishment. Nicholas Schork, director of research at the Scripps Genomic Medicine Program, recalls Topol ruffling feathers around 1990 when the two met at the University of Michigan. At the time, Schork was a graduate student called upon to help analyze an insurance database. Topol suspected too many bypass procedures were being performed and that surgeons weren't following guidelines to determine if the procedures were warranted. The study indeed showed that bypass procedures were being done more often than they should be. It looked at regional differences in the use of bypass procedures, differences by type of hospitals, and the dollars involved. Schork says it was a "hot potato." The study was eventually published, he says, but it took a while because editorial boards were reluctant to run it.

"I thought, here's a man who wants to push the envelope a little bit," Schork says. "It wasn't

Topol appeared in a spread in GQ (*opposite*) with the musical performer Seal as one of the Rock Stars of Science, a campaign from Geoffrey Beene Gives Back to win support for accelerating the development of medical research from the bench to the bedside. Information on the campaign can be found at www.rockstarsofscience.org.

ROCK STARS OF SCIENCE ADS FROM GQ. PHOTO BY BEN WATTS FOR GQ COUTESY OF GEOFFREY BEENE GIVES BACK®

like he was doing it for fame. It was more a matter that this is the truth and let's get it out there. I thought that was a great quality to have quite frankly. He was clearly going to piss off his colleagues. I have respect for that."

But, Schork notes, the study also speaks to something else at Topol's core—the desire to put things to the test. Schork says vetting technologies, new drugs, and devices through clinical tests to answer the basic questions like "Does this drug save lives?" has long been Topol's bread and butter. But now, Topol is concerned about how can we make those more efficient so we can get quality drugs out there to save people's lives. "This is something that's very near and dear to him. Can we leverage genetics and genomics? That's one question—can we design drugs or trials that target people with certain genetic profiles," says Schork. "The other one is to maybe leverage wireless technologies. Instead of having people come back every six months to have their blood pressure taken, why not give a little band-aid device that measures blood pressure 24-7. Maybe you don't need 10,000 patients in a study because you'll have so much data."

Marrying wireless technology with genomics is clearly on Topol's radar. Topol, who also serves as the chief medical officer of the newly established West Wireless Health Institute, which is exploring applications of wireless technologies to advance human health, sees an opportunity to tap into the vast network of wireless companies in the region. Initially, he had talks with Don Jones, vice president of health and life sciences for the San Diego wireless giant Qualcomm. The discussions covered what Scripps might be able do with the technology, but Scripps was constrained by resources. That changed when Topol began treating Gary West, a man who made his fortune in telemarketing. West quickly discovered he and Topol shared a mutual interest in wireless medicine. "He's passionate about changing the way medicine is practiced today," says West. "He thinks it's just wrong."

The belief that the current practice of medicine is dysfunctional is driving The West Wireless Health Institute, which will be housed on the Scripps campus, about 200 yards from Topol's office. Though its home won't be ready for occupancy until October 2009, the institute was spending the summer gearing up for its first clinical trial. The study will seek to reduce heart-failure readmission through the use of technology developed by San Jose, California-based Corventis. Corventis' device, which looks like an oversized band-aid and sticks to the chest, continuously measures heart rhythm, fluid status, respiratory rate, activity, position, temperature, and heart rate variability.

A recent study found nearly 27 percent of Medicare patients with heart failure, after being discharged from a hospital, are readmitted within 30 days. That revolving door costs the healthcare system an estimated $10 billion annually. The hope is that the device, by providing doctors with an early warning of worsening symptoms, can notify a patient to come in for preemptive treatment before they have another incident. Topol sees similar wireless sensors being developed to do everything from monitoring sleep disorders, to providing people concerned about their weight with real-time reports on their cell phones about their caloric intake and physical activity.

"Genomics only tells about biology," says Topol. "In any given person, all I can say is they have a predisposition to atrial fibrillation or sleep disorders or this or that. With physiology—the elegant phenotyping we've never been able to do before—we can have an entire ICU in someone's home monitoring all of their vital signs. It gives us a different look at a patient. It gives us their continuous physiology."

It is that marriage of genomics and wireless—biology and physiology—that Topol believe sets off Scripps from other research centers. There are plenty of what he calls "gene hunters," centers that do sequencing, identify genes that may be involved in disease, and publish their findings out for others to follow up on. But for Topol, it is the convergence of technologies, the ability to do the translational work, that is so powerful.

"The end strategy is changing medicine, says Topol. "You can't just find a gene and put it out there. That doesn't change medicine at all. You have to actualize that information, like what we're doing with the saliva genotyping with Plavix. You can't just show that the wellderly have these protective genes if you don't go beyond that. That's a nice, fascinating discovery that we hope to have, but you got to drill down to much, much more than that."

Changing medicine is no small goal, but it is a worthy one. And Topol is by no means seeking to do this by himself. He is marshalling the resources not only of Scripps, but also of the surrounding biomedical and technological talent in the greater San Diego area to do so. There will be financial, scientific, and even cultural obstacles along the way, to be sure. But then again, they don't call Topol a rock star for nothing. TJOLS

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SHAWNA KIRBY

Preventive Medicine

As our ability to sequence genetic data surpasses our ability to interpret it, regulators across the globe are taking steps to put rules in place on direct-to-consumer genetic tests.

By Marie Daghlian

In today's do-it-yourself culture, it's no surprise the power to analyze DNA would sooner or later be handed to consumers. But with anybody now able to spit into a tube and supposedly find out a possible genetic predisposition to cancer, Parkinson's, and other formidable diseases, society is increasingly asking a key question: is the technology ahead of our ability to truly understand it? In June of 2008, 13 direct-to-consumer genetic testing companies, as the marketers of these screenings are called, received cease-and-desist letters from the California Department of Public Health. The agency was seeking proof of compliance with state standards, including evidence the tests they were selling to California residents had been ordered by a physician and were processed by certified labs. They were given two weeks to submit proof that they were in compliance. It was a clear signal that regulators were ready to crack down on the rapidly growing business.

California is not alone. New York has gone after several companies for offering tests without a doctor's consent. In fact, it is the only state where a customer must get a doctor's authorization to get a paternity test. And Germany passed legislation in May that severely limits the use of genetic testing, except by a licensed doctor following the patient's consent. The move essentially bans most direct-to-consumer testing in the country. Paternity tests will only be allowed if both the woman and the man agree to be tested.

> We are against the idea of genetic exceptionalism where genetics has to be treated somehow special and different from everything else, in terms of regulation. Whether these tests should be treated differently because they are genetic rather than anything else is questionable.
>
> *—Carolyn Wright, Head Scientist, PHG Foundation*

Until recently, most genetic tests have remained in the purview of medical professionals. But since the mapping of the first human genome in 2003, a dramatic decline in the cost of sequencing has led to a rapid growth in researchers' ability to associate certain genes with certain diseases. One result has been a surge in the number of companies offering genetic tests directly to consumers, promising to reveal a variety of information including verifying the identity of a father, determining the diet that best suits an individual, discerning a person's athletic prowess, laying out a person's ancestry, and assessing someone's risk for various health conditions. Genetic tests for more than 1,300 diseases are already available clinically and could theoretically be offered directly to consumers in the future.

But while there have been dizzying advances in researchers' ability to annotate the genome, their ability to make sense of just what all this data means remains at an early stage. This has raised concerns around the world among scientists, clinicians, policy makers, and even many of the early genetic testing companies themselves that some form of regulation is needed to protect consumers from misleading claims and practices. Their concerns include the accuracy of the information, how it is communicated to

I suspect that the front-running companies probably have an intrinsic interest in keeping their noses clean, but as more and more companies start flooding the market, I suspect that some form of regulation is going to be required.

—Chris MacDonald, Professor, Saint Mary's University in Halifax, Canada

consumers, and whether or not the information delivered is useful.

But not everyone is happy about the new restrictions. When Germany passed its legislation in May, it essentially banned the sale of direct-to-consumer genetic tests, prohibiting employers and insurance companies from using genetic tests to discriminate, and restricting men from using such tests to determine whether they fathered a child without the consent of the mother. The German Medical Association warned that the law might lead people to go abroad to get testing done. The United Kingdom-based PHG Foundation, an independent non-profit organization focused on evidence-based biomedical science, issued a formal commentary, which said the German law represents a "regressive and paternalistic approach that takes genetic exceptionalism to an extreme not seen in other jurisdictions."

Carolyn Wright, PHG's head scientist, says, "We are against the idea of genetic exceptionalism where genetics has to be treated somehow special and different from everything else, in terms of regulation. Whether these tests should be treated differently because they are genetic rather than anything else is questionable."

Wright thinks genetic information is not that private. Ninety-nine percent of DNA is common to the whole population. And while she agrees the clinical utility of genetic tests remains unproven, she feels that Germany has gone too far. She would rather see something gentler, like a professional code of conduct. "I guess we think there should be some sort of oversight that broadly protects the consumer from quackery and fraudulence and allows them to take an autonomous position in relation to their own health," she says.

Carolyn Wright, PHG head scientist, favors a professional code of conduct rather than blanket legislation aimed specifically at genetic tests.

The current European regulatory framework does not cover an independent evaluation for genetic tests before they are marketed. Most direct-to-consumer tests are freely available. In the United Kingdom, the Human Genetics Commission is developing a voluntary framework to protect consumers from direct-to-consumer genetic testing, taking a more moderate approach. The Human Genetics Commission is drafting a common framework of

principles that are expected to include consideration of clinical validity and utility of different tests, the level of information provided to consumers, quality assurance, data protection and consent. The U.K.'s National Health Service has also initiated a pilot program to teach NHS scientists to train doctors and clinicians in genomic medicine.

In the United States, most laboratories are subject to quality control by Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments. Otherwise, there has been little regulation of the nascent but growing market for direct-to-consumer genetic tests. A handful of tests have been submitted and approved by the U.S. Food and Drug Administration, but most direct-to-consumer genetic tests are not submitted, exploiting a loophole in U.S. Food and Drug Administration regulations because they are not actually medical devices. There are efforts, however, to increase FDA oversight in this area.

Most people agree that some form of regulatory oversight is needed. The question is what kind of oversight and how much. Business ethicist Chris MacDonald sees no cause for panic. The main concern, from a business ethics point of view, is truth in advertising, says the professor in the department of Philosophy at Saint Mary's University in Halifax, Canada. Do people understand what they are signing up for and are they getting what they are paying for? He agrees that labs should be certified. He shares the skepticism of many biologists about whether there's any information being provided through the tests that's really valuable. But it also depends, he says, on what someone perceives as valuable and what they are led to expect. No one thinks to regulate the self-help

A lab worker at Navigenics begins to test a sample. The company favors some oversight because it is concerned about the effects irresponsible companies could have on the sector.

book market, he says, as long as authors act in good faith and are not actually telling lies.

"I suspect that the front-running companies probably have an intrinsic interest in keeping their noses clean in those regards," MacDonald says, "but as more and more companies start flooding the market, I suspect that some form of regulation is going to be required."

Amy DuRoss, vice president of policy and business affairs at Navigenics in Foster City, California, favors some oversight. "We've spent a lot of time and energy developing our practices and we want to make sure that there aren't any difficulties in the space because there will always be some irresponsible actors," she says.

We've spent a lot of time and energy developing our practices and we want to make sure that there aren't any difficulties in the space because there will always be some irresponsible actors.

—Amy DuRoss, Vice President of Policy and Business Affairs, Navigenics

Navigenics' Amy DuRoss says her company encourages customers to consult a doctor or genetic counselor to interpret test results.

She would like to see a third party entity established to regulate the utility of the markers used for genetic profiling. She is concerned that companies are marketing genetic tests that purport to give dating and nutritional advice based on a person's genes. Ideally, the third party would be part of the National Institutes of Health or the Centers for Disease Control and Prevention and be an independently funded platform for testing services. She would also like to see the Centers for Medicare and Medicaid Services take a more active role, perhaps by creating a genetic testing subspecialty under the Clinical Laboratory Improvement Amendments or CLIA.

Navigenics says it encourages customers to use its genetic counseling services, which are free of charge. Navigenics and its competitor 23andMe maintain they are clear in their informed consent agreements that they are not offering a predictive diagnostic and that their services are only informational and "not intended to be medical advice."

Like Navigenics, Mountain View, California-based 23andMe was one of the genetic testing companies that received cease-and-desist letters from the California Department of Public Health last summer. Both companies say they were already in compliance with state law when they received the letters. Nevertheless, a year after receiving it, 23andMe took the lead and drafted its own regulations in a bill that was introduced into the California legislature by Alex Padilla, a Democratic state senator representing Van Nuys, California. The legislation seeks to exempt gene-testing firms from requirements faced by other kinds of lab tests. It also adds privacy protections for consumers.

"They are working to develop regulations for a new class of product. I think they call this "post-CLIA genetics information service provider," says Jesse Reynolds, director of the project on biotechnology and the public interest at the Center for Genetics and Society in Berkeley, California. He thinks direct-to-consumer genetic tests raises a number of problems and fears this new type of product could fall between the cracks of existing rules.

He argues that 23andMe is really in the business of compiling and reselling data

sets. Ann Wojcicki, co-founder of 23andMe, is the wife of Google co-founder Sergey Brin, and Google is an investor in 23andMe. "Down the road, there are a lot of concerns about privacy," he cautions. "The role of Google should raise some eyebrows. Of course they are separate companies, but Google is a primary investor in 23andMe. Google is amassing a huge amount of information, including getting into the health records management business. Where could this go? Do we want to have large central databases that not only have our genetic information but our health records and our internet habits in one central location?"

Concerns about Big Brother aside, Wojcicki has been open about the need to amass large amounts of genetic data in order to make valid comparison studies and increase the understanding of the genetics underlying disease. The company's consent form states that 23andMe will use the data for research purposes.

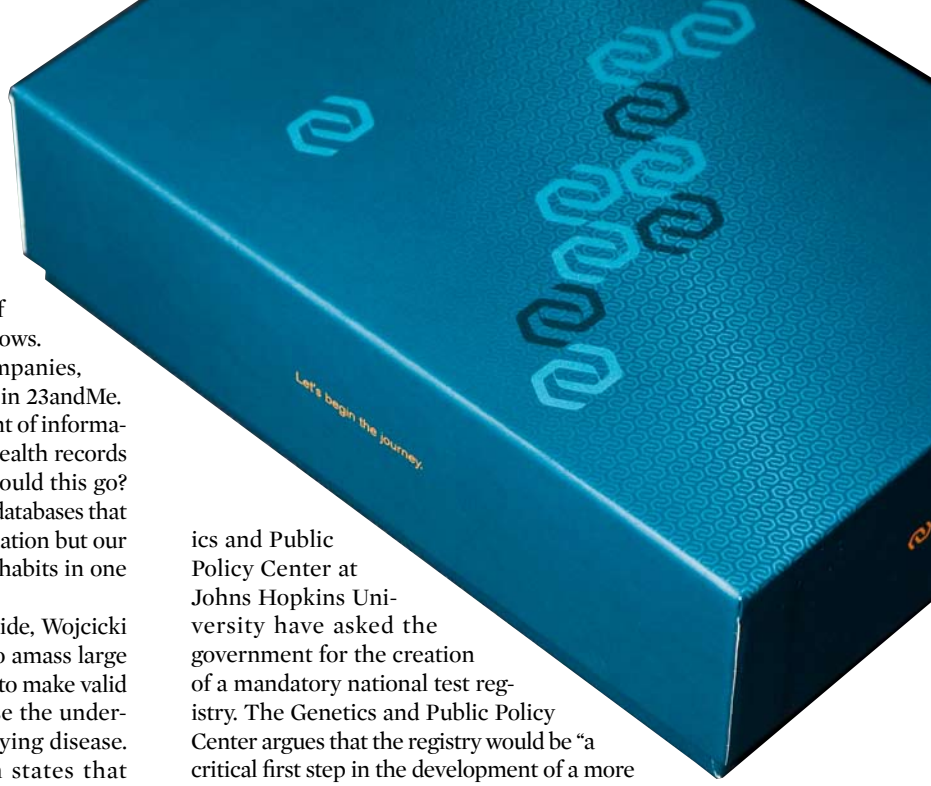
Still, Reynolds doubts that customers understand what they are getting into. He feels that 23andMe removes the expertise of doctors and genetic counselors. "They don't say 'we don't have doctors,' instead they talk about 'democratizing personal genetics.'" He says 23andMe and other direct-to-consumer personal genetic companies are trying to have it both ways, advertising tests that include information that he says is medical in nature, but telling regulators that what they provide is for educational or recreational uses.

Scientists are also skeptical about the usefulness of many of the tests. The American College of Clinical Pharmacy published a position statement calling for federal oversight of direct-to-consumer genetic testing companies, claiming that the Clinical Laboratory Improvement Amendments do not address the clinical validity of a particular test. It also asks the FDA to actively monitor compliance with regulations for advertising and marketing. The American Medical Association has recommended that genetic testing be carried out under the supervision of a qualified healthcare professional. The group also asked that physicians be provided with more information on the types of genetic tests available so that they can effectively counsel their patients.

Both the Washington, D.C. advocacy group Genetic Alliance and the policy group Genetics and Public Policy Center at Johns Hopkins University have asked the government for the creation of a mandatory national test registry. The Genetics and Public Policy Center argues that the registry would be "a critical first step in the development of a more transparent, quality-centered system of oversight that will better inform and protect the public." In the blueprint it presented in a policy paper in the journal *Public Health Genomics*, they want the FDA and CLIA to give Health and Human Services the authority to establish the registry, which would eventually reside under the auspices of either National Institutes of Health or the FDA. The registry would initially be limited to genetic tests that are health-related. It would contain information for assessing a test's reliability, how results relate to current and future disease risk or health status, and how useful the results are in informing further action on the part of the test taker or healthcare provider.

A joint Centers for Disease Control and Prevention/NIH workshop convened at the end of 2008 has also added its voice to a growing body of expert recommendations for the evaluation and regulation of personal genomics services.

While policymakers in the United States struggle to come up with appropriate oversight and regulation for direct-to-consumer genetic tests, a regulatory hole remains that's proven difficult to fill. The regulatory issues are complex and will take some time to resolve. In the interim, the responsibility to fill the regulatory void will fall on state governments, which will have mainly their truth-in-advertising statutes as their primary tool. That may leave them busy with a burgeoning industry as they try to hammer nails with a screwdriver. TJOLS



A test kit produced by Navigenics.

Bosom Buddies

Women undergoing treatment for breast cancer find shared experience leads to lasting bonds and an unexpected support system.

By Kristi Eaton

Most people would stay as far away as possible from where they were infused with drugs to fight cancer. But three years later, Marilyn Young still returns to the Victoria, Texas doctor's office where she sat every week watching the drug enter her body, and she does it by choice.

Why relive a nightmare? Young wants to reconnect with other women who currently battle or battled a certain aggressive form of breast cancer known as HER2-positive. The name refers to a mutation in the HER2 gene, which overproduces a protein that fuels tumor growth. Like the other women who go to the office for treatment, Young was treated with Herceptin, a drug that has perhaps more than any helped popularize the notion of personalized medicine. Herceptin was among the first examples of a therapeutic approved by the U.S. Food and Drug Administration requiring the use of a companion diagnostic to determine its appropriateness to a patient.

But Herceptin has given rise to another personalized medicine trend of its own. It's had the

unexpected effect of bringing together women in communities across the nation who use the drug in ad hoc support groups under the banner of the HER2 Sisterhood. Young, 64, was one of seven women at the oncologist's office at the time who was being infused with Herceptin. As the office scheduled the infusions for Herceptin patients at the same time every week, the women would find themselves in a room together for an hour at a time. A conversation would start up. Soon, the women decided to make the get-togethers official: They organized their own local HER2 Sisterhood. Every Wednesday, Young would gather with the other women for their infusions and share their stories. Topics covered were as often personal as they were medical. And despite the rather grim setting, the women sometimes found themselves cutting up. During these group laughing fits, Young occasionally worried the noise was getting out of hand. But, she says, the doctors and nurses wanted them to enjoy themselves. "It was good for patients suffering from other forms of cancer to see it was still possible to laugh," she says.

Young says that over the course of their treatments, the women became close friends. Just because some of the womens' treatments had ended, it didn't make sense to stop seeing each other. And the doctor in the office encouraged the bonds, she says."We'd tell some of our symptoms of the other chemo," she recalls. "We talked on all subjects. We introduced our families to each other. We knew some had children of different ages," she says of the women who ranged in ages from 40 to 83. The chit-chat, she says, was a way for the women to forget about what they were going through.

The birth of the HER2 Sisterhood actually dates back to 2001 when a simple conversation between two breast cancer patients undergoing treatment in Bakersfield, California gave rise to the group.

Nancy Pelton, a tax accountant who had suffered a recurrence of HER2-positive breast cancer after having been treated with a combination of chemotherapy, radiation, and paclitaxel, found herself battling the disease again. This time, though, doctors had a new weapon. Though Herceptin was first approved in 1998 when Pelton was originally diagnosed, it was only approved for use in patients with a recurrence of the disease. When it returned, she was finally treated with weekly infusions of Herceptin.

At one of the infusion sessions, she met another woman undergoing the same treatment at the same time. The two struck up a conversation. Soon enough, they were laughing and having what Pelton describes as a "good time." Around that same time, a third woman began Herceptin treatments and ended up in the conversations. From there, the HER2 Sisterhood began to grow.

> By having different ladies in different stages that have gone through treatment, we are able to answer questions for people just starting out who have lots of questions and offer support in that way. We're a very nontraditional support group.
>
> *—Nancy Pelton, founder of the HER2 Sisterhood*

"We offer something that a traditional support group doesn't offer because we're just specifically HER2-positive," Pelton says. "By having different ladies in different stages that have gone through treatment, we are able to answer questions for people just starting out who have a lot of questions and offer support in that way. We're a very nontraditional support group."

Today, between 20 and 25 women ranging in age from the late 20s to nearly 70, keep in touch, with five to 15 taking part in regular dinners together.

Genentech, which manufactures Herceptin, took notice of the women's unique bond. The South San Francisco-based biotech has since sought to promote the formation of other such groups among the drug's users through its HER Connection website. The website offers a "HER2 Sisterhood Tool Kit" for download. The company says it's only aware of two such groups.

"This organic group formed into a peer-to-peer support system that provides support in a non-traditional way," says Erica Jefferson, a spokeswoman for Genentech.

Living Beyond Breast Cancer, a national education and support group for breast cancer patients, helped Genentech gain information and viewpoints from HER2-positive patients

The HER2 Sisterhood members from Bakersfield, Califronia regularly get together for dinner and to share stories about their lives.

to make the HER2 Sisterhood as effective as possible. Elyse Caplan, education director for Living Beyond Breast Cancer, says there are many types of breast cancer. Patients with each subtype need their own resources and support, she says.

"As science and medicine begin to personalize treatments, we want to make sure our education and resources parallel that personalized track," she says.

Caplan says women with the HER2-positive breast cancer—about 20 percent of the estimated 175,000 to 200,000 breast cancer cases diagnosed each year—feel isolated because they know their breast cancer is more aggressive than other forms of the disease. "They have worries, 'Is this treatment going to eradicate this disease?'" Caplan says. 'Will I have a recurrence? What does it mean to live with the fear of a recurrence?'"

Trying to answer those questions is one of the reasons Pelton says she stays very involved in the group, despite being cancer-free for years.

"I like being able to help other people because I'm 10 years out now," Pelton says. "I try to stay up to date on facts because I know how scared a person is when they start treatments and don't know what's going on with some of the side effects. That's one of the reasons I enjoy still having the group and keep at it."

It's been actually a joy to see all the different people of different walks of life. It kind of opened my life up. It made me a stronger person because of it.

—Marilyn Young, a member of the HER2 Sisterhood in Victoria, Texas

Group members admit an unusual sense of loss when someone in the group finishes their treatment. There's also sadness when they themselves near the end of their own treatment, they say. The fear is they'll never see their friends again. But that's not the case. These women continue to get together long after their treatments end.

In Victoria, Texas, a group of women—10 of the 33 who went through the treatment as part of the HER2 Sisterhood—reconnect regularly. They meet up to talk about their lives, share laughs, and visit with each other. Sometimes, the oncologist or a Herceptin representative provides the snacks for the group.

Nancy Pelton, (*lower right*) founded the HER2 Sisterhood in 2001 after a chance conversation with another woman who was being treated for HER2 positive breast cancer.

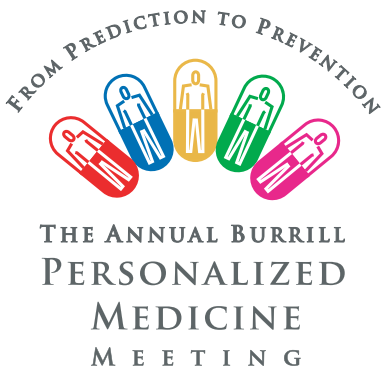
Some of the women have had recurrences and are going through the Herceptin treatment once again. But Young, the patient from Texas, remains positive. She says spending time with the other group members who came from different backgrounds has been rewarding, too. "It's been actually a joy to see all the different people of different walks of life," she says. "It kind of opened my life up. It made me a stronger person because of it."

A diagnosis of breast cancer can be devastating, particular a diagnosis of the disease as aggressive as HER2-positive. Though the HER2 Sisterhood may have developed through chance circumstances, oncologists should take note of the value patients find in the support they draw from each other and the importance they place on feeling not like a cancer patient, but a person. TJOLS

The 5th Annual Burrill

Personalized Medicine Meeting

November 9–10, 2009
San Francisco, CA



The Annual Burrill Personalized Medicine Meeting encompasses detailed discussions on the whole spectrum of personalized medicine—from prediction to prevention. The two-day event will also provide attendees with a detailed "window" into the emerging personalized medicine world as seen by leading experts and decision makers in the field including:

Dr. Margaret "Peggy" Hamburg
Commissioner, U.S. Food and Drug Administration

Dr. George Poste
DVM, PhD, Chief Scientist, Complex Adaptive Systems Initiative; Regents' Professor and Del E. Webb Distinguished Professor of Biology, Arizona State University

Dr. Leroy Hood
MD, PhD, President, Institute for Systems Biology

This conference intends to explore the world of personalized medicine as it stands in 2009 and as it will develop in the next 3- to 5- year timeframe. Although science forms the basis for these exciting developments, this is not a science conference. Instead, our aim is to bring together stakeholders from across the value chain of personalized medicine for a fascinating and instructive set of 'conversations' with experts in all these areas...

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Fitting Into My Genes

Research into the genetics of anorexia may lead to new treatments, keep people with the eating disorder from feeling guilty, and help others understand there's more to the disease than little girls seeing too many pictures of rail-thin models.

By Kristi Eaton

They told me to keep it a secret. Nobody will understand, the doctors, psychologists, and therapists all said. It's an illness to be ashamed of they seemed to conclude.

So, at age 11, four feet nine inches tall and 54 pounds, I tried to hide my anorexia from classmates and society at large. Looking back, I don't think I was fooling anyone, what with my skeletal arms and legs, pale skin, and sunken eyes. Not to mention the fact that I threw my lunch away most days, became emotional at the drop of a hat, and was sometimes taken out of school for days at a time. But those symptoms could be taken as signs of another illness, such as cancer. With people lacking a definitive answer to what was slowly destroying my body, rumors swirled, making the turbulent years of middle school even more volatile.

Anorexia nervosa, characterized by extreme weight loss through excessive dieting or exercise, a distorted body image, and an intense fear of gaining weight, is an illness that affects as many as 10 million females and 1 million males in the United States. Anorexia has the highest premature fatality rate of any mental illness and, according to some studies, people with anorexia are up to 10 times more likely to die compared to those without the disorder. The most common complications that lead to death from the disorder are cardiac arrest, electrolyte and fluid imbalances, and suicide. The disease is more often than not coupled with depression.

Twelve years ago, at the height of my struggle with the disease, I sometimes wished I had cancer. The cause of cancer, at least, could be traced to biology, I thought. Nobody chooses to have cancer. It chooses them. That's much easier to explain to people than why I was slowly trying to kill myself by exercising up to eight hours a day and not eating. I couldn't even explain to myself why I did what I did. I couldn't figure out how I had changed from being a happy child who enjoyed eating chocolate chip ice cream and Doritos to a ball of nerves that kept a detailed calorie intake and exercise journal.

For decades, researchers believed anorexia was an illness primarily caused by societal factors like media images of impossibly trim models, as well as psychological factors, such as low self-esteem or feelings of a lack of control in life. Although studies are proving otherwise, many still believe anorexia afflicts only upper-middle class Caucasian females during their teenage years. Often people view it as a disease born of selfishness, greed, and vanity.

I sometimes wished I had cancer. The cause of cancer, at least, could be traced to biology, I thought. Nobody chooses to have cancer. It chooses them. That's much easier to explain to people than why I was slowly trying to kill myself by exercising up to eight hours a day and not eating. I couldn't even explain to myself why I did what I did.

"You just want attention," some people would say. Or, "How can you starve yourself when you are well off and so many people go without in this world?"

I wish I could have had an answer for them. Maybe soon I will. It turns out that to determine the cause of anorexia, researchers will have to go beyond psychological and environmental factors to include biological and genetic

(*Opposite*) Author Kristi Eaton at age 11 when she began a four-year battle with anorexia. Her weight dropped to 54 pounds.

(*Above*) Eaton, 24, no longer suffers from anorexia, but she knows it is something that will affect her the rest of her life.

components, as well. And as with a number of other disorders from depression to obesity, new research into the role genetics play is helping change perceptions about people who suffer from the illnesses. And this better understanding could lead to more effective treatments.

Consider that people with an immediate relative suffering from depression are two to three times more likely to suffer from the illness as well, research shows. Multiple genes and multiple modes of inheritance are believed to be involved in depression. Although personalizing depression treatment based on genetics is a ways off, researchers say the day where a simple cheek swab of cells can inform a doctor about the best possible medication to treat the illness is a distinct possibility.

Studies tying genetics to anorexia suggest the same possibilities for more targeted treatments for the eating disorder. In 2002, Dutch researchers released a groundbreaking report showing a relationship between anorexia patients and a particular gene mutation. While studying the DNA of 145 patients, the scientists discovered that 16 of them were carrying a mutation of the gene that manufactures Agouti Related Protein, a substance in the brain that stimulates the desire to eat.

More recently, a 2006 study published in the *Archives of General Psychiatry* found that complications during and immediately after birth are associated with the development of anorexia and bulimia, an eating disorder where the patient binges and purges to maintain or lose weight. The researchers noted that a child's risk of developing anorexia or bulimia increased if the mother was found to suffer from maternal anemia—low levels of hemoglobin in the blood—or diabetes mellitus and placental infarction—death of part of the tissue of the placenta.

Just this July, researchers at Chiba University in Japan discovered that women suffering from anorexia have lower levels of the brain protein BDNF compared to healthy women. Women with low levels of the protein in their blood had the lowest self-image, suffered from anxiety and depression, and performed poorly on certain tests of cognitive ability, according to the researchers. Moreover, the scientists noted that women who overcame the disease had higher levels of BDNF, suggesting that the protein levels may be reversible.

Such studies are helping researchers better understand the biological pathways and biomarkers affiliated with anorexia, which could then lead to identifying medications or approaches to reverse the features of the illness, says Cynthia Bulik, director of the University of North Carolina's Eating Disorders Program. "At some point we could conceivably find that anorexia is not a single illness, but that different biological pathways might lead to the same endpoint," she says. "Theoretically, tailoring of treatment to biological underpinnings could then be possible. This is down the path."

Recognizing biological factors would help doctors identify individuals who are at risk for developing the disease, she says. Physicians could be especially vigilant and intervene more quickly when patients show some telltale signs: falling off the growth curve or participating in excessive exercise.

Such awareness of the illness' progression might have saved me from spiraling down into the disease. As my body quickly deteriorated, my pediatrician was at a loss for what was wrong with me. Looking at weight and height charts, I was considered average in height but was around the third percentile for weight for females my age. In other words, I weighed less than 97 percent of the females my age. Blood tests were done on me to rule out a spate of diseases before doctors settled on a diagnosis of anorexia nervosa, depression, and obsessive-compulsive disorder.

Three hospitalizations, countless medications, and numerous sessions with counselors, psychologists, and doctors followed over the next four years until one day, I decided I didn't want to live the way I was living. I call it "my epiphany." I still vividly remember waking up one morning and realizing I wanted to be like other kids. I wanted to eat pizza. I wanted to laugh. I wanted to get through a day without exercising if I didn't feel like doing so, and without crying.

My epiphany changed things, but, as with cancer, I couldn't simply turn off the biological and genetic components of my disease. Medication has helped the depression and obsessive-compulsive disorder, which, in turn, has helped the anorexia. But I still struggle with the eating disorder every day and know I will battle it for the rest of my life. I'm confronted with it each day, whether it's eating dinner or waking up and taking my medication first thing each morning. I know I'm never going to be cured. I can only hope to continue to be in recovery and share my story so others are not ashamed as I once was. TJOLS

The Burrill Consumer Digital Health Meeting

A convergence of technologies and opportunity

Save the Date! March 22–23, 2010

The days are near when PDAs and smart phones will not merely be communication devices, but also personal healthcare assistants capable of receiving vital signs and even body fluid samples for analysis and transmittal of results. Wherever patients are in the world, they will be able to connect with their physicians. And their doctors, in turn, will be able to practice medicine virtually anywhere and at anytime, with instant access to the information and systems they need—right at their thumbs.

In order for this new digital health world to become, a reality a number of challenges will have to be overcome. Professionals who implement the new system will have to work with an aging population, diminishing human resources, and a growing patient safety concern. They will also face a heightened responsibility for keeping patient information private and secure.

Mindful of these changes and challenges, Burrill & Company, in association with the University of Illinois/Mayo Clinic partnership, is for the first time holding The Burrill Consumer Digital Health Meeting to help prepare the life sciences community for this exciting new era.

For more information visit our website:

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