

SPECIAL INTELLIGENCE BRIEFING!

Understanding the genomic/proteomic revolution and how it will reshape medicine!

From the Desk of R. Lewis Dark...

THE **REPORT** **REPORT**

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY
FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTS

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A Special Briefing by THE DARK REPORT

Grasping the Impact of the Genetic Revolution

It's an insider's view of far-reaching changes expected to create new opportunities for labs

IT'S BEEN SEVEN MONTHS since healthcare futurist Rick J. Carlson shared his insights about the impending genomic/proteomic revolution at the *Executive War College* in New Orleans last May.

A key theme of his message was that diagnostic services would be squarely in the middle of the coming genetics tidal wave. Carlson, President of **Health Strategies Group** in Aspen, Colorado, believes that clinical laboratories and pathology groups are well-positioned to provide clinical services rooted in genetic knowledge.

But it was Carlson's other predictions about how genetics will transform today's healthcare system which caught the attention of *War College* attendees. In the months since his remarks, THE DARK REPORT has fielded comments and requests for more from Rick Carlson.

Because this topic is complex and cannot be properly summarized in a short story, THE DARK REPORT is devoting this entire issue to the topic of genetic

knowledge and how Rick Carlson believes it will transform all aspects of society. The "bad news" is the American healthcare system will be totally transformed by genetic knowledge. The good news is that Carlson believes the most substantial of these changes won't occur for as long as ten more years.

As part of THE DARK REPORT's mission to help laboratory executives and pathologists stay on top of key trends affecting their laboratories, we are proud to present this exclusive, in-depth interview with Rick Carlson. The intelligence briefing which follows provides a useful roadmap for long-term strategic planning.

It is also relevant to know that, in the intelligence briefing which follows, Carlson provided a depth of information not found elsewhere in print on the subject of how genetics will transform healthcare and society. It is this type of "insider intelligence" which makes THE DARK REPORT an invaluable resource for perceptive laboratorians.

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Newsmaker Interview...

“Clinical laboratories and pathology groups are at the leading edge of the genetic revolution.”
—Rick J. Carlson.



Rick J. Carlson

Laboratories Sit Squarely Between New Genetics and Today's Medicine

One consequence of genetic knowledge is that consumers will begin buying individualized healthcare services

CEO SUMMARY: Healthcare futurist Rick J. Carlson believes that knowledge of the human genome will trigger revolutionary changes in the American healthcare system. In particular, Carlson predicts consumers will drive the primary shift in the way healthcare services are organized and delivered. As this occurs, he believes clinical laboratories and pathology groups are perfectly positioned to serve the changing needs of consumers and their physicians. At this year's *Executive War College*, Carlson's insights and predictions captured the crowd. In response to requests for more information from him, THE DARK REPORT arranged this exclusive interview. Because of Carlson's unique access to many of the nation's thought leaders in healthcare, business, and politics, his views represent a highly credible view of how and why the genetics revolution will change the healthcare system as we know it today.

IF RICK J. CARLSON'S CRYSTAL BALL proves accurate, diagnostic laboratories and pathology group practices will be the focal point where new genetic knowledge collides with traditional healthcare policies and practices.

Carlson is well-qualified to make this claim. He is President of **Health Strategies Group** of Aspen, Colorado. Carlson has long-standing credentials as a healthcare "futurist." He was part of the

Jackson Hole Group which, in 1974, developed the concept of the healthcare management organization (HMO) that was incorporated into major federal legislation that year.

He's written several well-received books on healthcare. In April this year his latest book, *The Terrible Gift*, hit bookstores. Co-authored with Gary Stimeling, it is a comprehensive look at how genetic technology will profoundly reshape society and the American healthcare system in unexpected ways.

Carlson's insights are part of an ongoing research project funded by a major grant from the **Robert Wood Johnson Foundation**, Carlson is principal investigator of the "Understanding the Human Genome Project." He is studying how knowledge about the human genome will change healthcare and affect society. Carlson's direct research has spanned three years. During this time, he's met with more than 600 of America's most prominent leaders in healthcare, business, academia, and government.

He has two startling conclusions from this extensive effort. "First, across all sections of our society, I've found most leaders are not prepared to deal with the serious issues triggered by knowledge about the human genome," declared Carlson.

"Second, consumers will be the most powerful force driving profound changes to our healthcare system for an obvious reason: they want access to the health and lifestyle benefits that are promised by genetic-based technologies," he said.

At this year's *Executive War College* in New Orleans, Carlson's insights and predictions made a profound impact on his audience of senior-level lab administrators and pathologists. He successfully connected the dots between healthcare's future—increasingly rooted in genomic technology—and today, where healthcare's earliest uses of genetic-based medicine are already forcing laboratories to react.

In the months since Carlson's appearance on the *War College* podium, THE DARK REPORT has received requests for more from Rick Carlson in a form that can be used to help laboratories and pathology groups in their long-term strategic planning.

To serve this interest, THE DARK REPORT recently sat down with Rick Carlson. The objective of this exclusive interview was to identify and articulate the impact of technology and the market drivers he's identified that will reshape the American healthcare system. The interview was conducted by Robert L. Michel, Editor-in-Chief.

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EDITOR: Could you set the theme for your message today? Our goal is to provide laboratories and pathology groups with intelligence they can use to shape the business and operational strategies of their lab organizations.

CARLSON: I'd like to discuss ideas that sweep across the entire range of the healthcare system. These ideas are not actionable today, but will generate change over a much longer time horizon.

EDITOR: What is the framing for these insights, predictions, and observations?

CARLSON: There is new knowledge accumulating in healthcare. Much of it is highly technical. However, many decisionmakers in healthcare are not technically-trained. Neither are they clinicians. For this reason, many healthcare leaders cannot grasp the implications of new technologies, particularly those involving human genetics.

EDITOR: In contrast, most laboratory administrators and pathologists are technically-trained and are directly involved in clinical services.

CARLSON: For them, the conflict will come because they grasp the ramifications of new healthcare technology, but, for example, the hospital administrators responsible for strategic decisions and capital spending may not.

EDITOR: Your point, then, is for our laboratorians to realize that, even though they may understand the immediate and long-term ramifications of new genetic-based medical technology, other decisionmakers in their healthcare system probably don't.

CARLSON: That's right. I embarked on this project because it was already

obvious that many healthcare leaders are unprepared to deal with the consequences of technology and clinical practices triggered by knowledge about the human genome.

EDITOR: Could you describe how you've researched this?

CARLSON: My research was organized to answer two questions. One, what did leaders in healthcare, business, academia, and government know about the field of human genetics? Two, if they didn't know, what were their questions about this field? Our intention has been, once we researched these questions, to develop educational programs which provide the answers to their questions.

EDITOR: How did you access these types of high-level leaders?

CARLSON: That's been easy. For example, we would go to major trade associations, such as the **American Hospital Association**. We would ask the executive leadership if they would allow us, at some upcoming big meeting, to do a workshop involving 40-50 of their key members.

EDITOR: That's a productive way to gather many thought leaders from one industry in one place at one time.

CARLSON: It did work exactly that way. Over the last three years, I've probably interviewed 600 people and did presentations to a wide range of groups, both in and out of healthcare.

EDITOR: Now for the jackpot question. Based on all this effort, what conclusions emerged about the impact of genetic technology on healthcare and society? What are the most important issues laboratories should track and

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incorporate into their long term strategic plans?

CARLSON: The major conclusion is that this is an immensely complex subject and few thought leaders are prepared to deal with the issues generated from new knowledge about the human genome. What I'd like to do is share with you seven fundamental dynamics directly linked to genetics. Each is interconnected and will influence healthcare and the way consumers use healthcare services. As a prelude to these seven points, I want readers to understand a fundamental attribute about the human genome project.



"I embarked on this project because it was already obvious that many healthcare leaders are unprepared to deal with the consequences of technology and clinical practices triggered by knowledge about the human genome."

EDITOR: Please do.

CARLSON: People today are bombarded with news reports about a wide range of scientific discoveries and new technologies that will change how we do things and how we live. I'd like to create a distinction that puts the human genome into a different category of knowledge.

EDITOR: Yes.

CARLSON: It is my contention that knowledge of the human genome makes us smarter about who we are and this knowledge will profoundly change human behavior in ways we cannot predict with precision. In my view, knowl-

edge of the human genome is transformational knowledge.

EDITOR: How is this different from other "types" of knowledge?

CARLSON: Use the Internet as an example. Technology that created the Internet and continues to make the Internet easier to use did not change human behavior as a result of making us smarter about ourselves. For the most part, we use this technology simply to make it easier for us to do things we were *already* doing.

EDITOR: In other words, it made our work more productive. In our personal lives, it allows us to shop and bank from our home computer, for example.

CARLSON: Yes. It eases existing patterns of behavior. Now contrast the Internet's technology impact with that of the human genome. As we understand the human genome, we are creating new knowledge about ourselves. You cannot roll that knowledge back, it is not a one-time bubble. It is cumulative and exponential. We are accumulating new knowledge daily—and it will not disappear.

EDITOR: What you are saying, then, is that the human genome is a class of technology and knowledge which makes us smarter, thus stimulating an unpredictable and continual cascade of changes to our society. In comparison, the technology of a new gasoline engine which gets 500 miles per gallon or technology which makes data transmission faster on the Internet improves life, but doesn't alter it in a fundamental way.

CARLSON: Conceptually correct. It is important to recognize that technologies adding to our knowledge of the

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human genome are increasing knowledge about ourselves. We will use this new knowledge about ourselves to change our individual lives and our collective societies in transformational ways.

EDITOR: Wow! You believe that knowledge of the human genome is, in and of itself, a revolutionary trigger quite unlike most of the scientific breakthroughs we've seen during the last century. Let's get into your seven key points about the impact of genetics.

 ▶ **Carlson's Key Point #1**
Medicine Will Be About Differences

CARLSON: My first point is this: the future of medicine will be devoted to providing individualized care to specific patients. *Medicine will be about differences!* This is a transformational concept. As lab managers and pathologists, your readers are familiar with differential diagnosis. They do clinical tests with the goal of identifying what will work with a specific patient. However, historically, medicine has been organized around a fundamentally different premise: in order to improve quality, care must be standardized. Essentially, we've been treating patients the same. That is why we do surgery on everyone at 6:00 a.m. That is why a drug like Claritin is prescribed for everyone exhibiting appropriate symptoms. For the most part, we've not personalized the delivery of that drug and many other types of healthcare services because we did not assume that the differences among people were important in achieving the desired clinical outcomes.

EDITOR: This is the philosophy that guided healthcare throughout the last century; standardize care to improve quality. Once it is demonstrated that certain treatment protocol works, the healthcare system tries to get all patients demonstrating those symptoms to be treated with that proven protocol.

CARLSON: Right. But now genetics allows us to understand how people are different, and how those differences account for their unique response to specific therapies. Here is where it gets interesting. Humans are 99% genetically alike. It is that 1% difference where the action will be.

EDITOR: Continue, please.

CARLSON: The *future* of medicine will not be in standardizing care in order to treat everyone the same. It will involve understanding why we are different and intervening in the difference. By the way, this sets us upon a collision course. Personalized medicine and quality based on standardization do not mix.

EDITOR: Rick, that's a provocative point. Today the efforts to reduce variability in how physicians provide care to patients are intensifying. That's perceived to be a path to higher quality. For example in the area of cardiology, the state of Rhode Island is pushing hospitals to insure that all inpatients receive the full, approved protocol, even down to measuring the number of cardiology patients that receive a prescription for aspirin upon discharge.

CARLSON: That is why the term "personalized medicine" has lots of implications. Today's healthcare system is not organized to individualize care.

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EDITOR: With more genetic knowledge about differences in how people respond to therapies, today's healthcare system is going to be tugged into some uncomfortable places. What's your next key point?

 ▶ **Carlson's Key Point #2**
"Sick To Better"

CARLSON: Observation number two might be simply stated as "sick to better." Today's healthcare system is organized to respond to people who become sick. Over time, this emphasis will shift toward helping people maintain better health with the aim of preventing them from becoming sick in the first place.

EDITOR: That's the shift from reactive medicine to proactive medicine about which you have spoken.

CARLSON: Correct. And it's genetics which enables this evolution. Traditional medicine is organized to deal with people when they become sick. Certainly there's always been a goal of helping people manage their help to enhance their quality of life. But the primary purpose of medicine was really to "fix the patient." To a significant degree, this will continue to be the objective of medicine in the future. However, healthcare has now begun its migration toward a system which can intervene to make sick patients better or prevent illness completely. This capability is fueled by our expanding knowledge about the human genome.

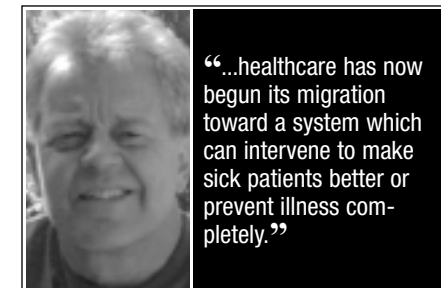
EDITOR: More specifically, how will knowledge about the human genome change the way healthcare intervenes in a patient's life?

CARLSON: In theory, the right knowledge and application of genetics

technology can allow us to make an individual perform better, such as in sports or similar activities. We can even improve appearance. There will be more vanity interventions. We have early clues as to how consumers will use these technologies.

EDITOR: Botox is an example of a vanity intervention. I've read that the single biggest group getting Botox injections are middle-aged men.

CARLSON: Viagra is another example which demonstrates how rapidly consumer thinking can change. From a global perspective, men have generally denied their own health problems. "Oh, there is nothing wrong with me. I could have a heart attack and just keep on going. I'll go to the hospital tomorrow because there are things I need to do today." Viagra got a lot of men out of denial. "Well, I do have a problem. I don't want to confess that I do, but I want that drug." Now the truth is that Viagra is fundamentally a recreational drug. Its true therapeutic use is relatively limited compared to the overall number of prescriptions.



"...healthcare has now begun its migration toward a system which can intervene to make sick patients better or prevent illness completely."

EDITOR: That's a fascinating insight. You are saying that consumers, once a genetic technology can improve their life, will demand access to that technology.

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CARLSON: That shouldn't surprise anyone. We are in the midst of a transition in how consumers think about healthcare and use the healthcare system. It is a shift away from thinking about it as something that only cures, fixes, and repairs. Increasing numbers of consumers are coming to view healthcare as something that could provide us a potent new medicine of the future which enhances lives, increases productivity, and improves performance; all good outcomes. But these have grave implications, from a social policy standpoint.

EDITOR: Is that why you titled your latest book *The Terrible Gift*?

CARLSON: In part, yes. The implications can be terrifying. Look at the nation's soccer moms and baseball dads. Couple the technological ability to enhance performance with the parents' desire to improve the lives of their young children. We will see lots of money spent by parents to improve the lives of their children in this way. This will be the real flame and bonfire under the consumer healthcare movement.

EDITOR: That explains how consumer expectations and demand will tug at today's healthcare system, which is focused on curing people who are already sick.

CARLSON: There is nothing more ferocious than a set of parents with money and time who want to improve their children's lives. Much of the yield in genomics technology will, in the early stages, be focused on the young. That is one reason why, in the hospital sector, children's hospitals throughout the United States are the early adopters of emerging genomic technology,

not academic centers or community hospitals.

EDITOR: That means pathologists and lab directors in children's hospitals will be the first to actively develop genetic-based diagnostics services in support of their institution's clinicians. What is your third key point?

 ► Carlson's Key Point #3
 New Healthcare Policy
 Crossroads Approaches

CARLSON: I predict we are approaching a social policy crossroads similar to one crossed at the turn of the last century. One hundred years ago, society was winning lots of public health battles. Water was cleaned up. New sewer systems reduced disease. Child labor was removed from the work force. At this crossroads, we collectively looked at our successes and asked "what next?" The decision was made to direct the healthcare system toward curing, fixing, and repairing.

EDITOR: Which resulted in a century where huge investments were made in building hospitals and other institutions to treat sick people.

CARLSON: Yes. Metaphorically, I describe hospitals as healthcare forts or castles. They are the bastions where patients can do battle with their particular disease. Our health system has spent virtually all its money fixing the problems of patients who've become sick. Little money has been spent to investigate the causes of these problems.

EDITOR: Do you believe, in the early years of this century, we will face a sim-

ilar strategic decision point in social policy affecting healthcare?

CARLSON: Definitely yes! Healthcare spending in the United States is approaching \$2 trillion per year. It is 20% of our GDP. The knowledge we are accumulating about the human genome will force us to reexamine our healthcare spending priorities. Might, say, an investment of 1% into the causes of disease and poor health trigger huge benefits to patients while reducing the social costs of healthcare? I can't predict the final outcome of this debate, but I already see its earliest manifestations among employers, payers, and the government.

EDITOR: By using the terms forts and castles to describe our health care campuses, I assume you see existing hospitals and health systems as valiant defenders of the status quo in healthcare. They want to maintain the emphasis on curing, fixing, and repairing, particularly if "prevention" would divert dollars away from their institution.

CARLSON: I definitely expect that reaction. The existing financial struggles in healthcare will make it tough for our largest healthcare institutions to take a leading role in moving from reactive medicine to proactive healthcare management.

EDITOR: That certainly has interesting consequences for pathologists and hospital laboratory directors. They are often first to recognize the clinical value of new diagnostic tests—which you predict will increasingly be used to identify high-risk patients *before* they get sick and need to visit the hospital. Rick, what is your fourth insight?

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 ► Carlson's Key Point #4
 Genetic Knowledge Will
 Go To "Sub-Atomic" Levels

CARLSON: Our knowledge of the human genome is going to lead us deep into a level of science which I will call "sub-atomic." Each level will exponentially expand our ability to improve a human's life and prevent disease or disability. With the completion of the basic map of the human genome, we've just cracked the first level of complexity. The next level appears to be the human proteome.

EDITOR: Is it like physics, which started with Newton's Apple and is continually moving to smaller units like the atom, and now to subatomic particles?

CARLSON: That is a parallel process. Think of it like making a map. Web sites like MapQuest now allow us to drill down from a map of the entire United States down to the level of a street, even a city block. As we crack each level of the human genome, we will be drilling down to smaller, more detailed life processes which trigger new knowledge—and the opportunity to intervene earlier to prevent disease or to enhance an individual's quality of life, performance, and appearance.

EDITOR: Can we move to your next key point, which would be number five?

 ► Carlson's Key Point #5
 Consumers To Drive
 Changes In Healthcare

CARLSON: I predict that consumers will be the ones to change our existing healthcare system because they will

(story continues on page 13)

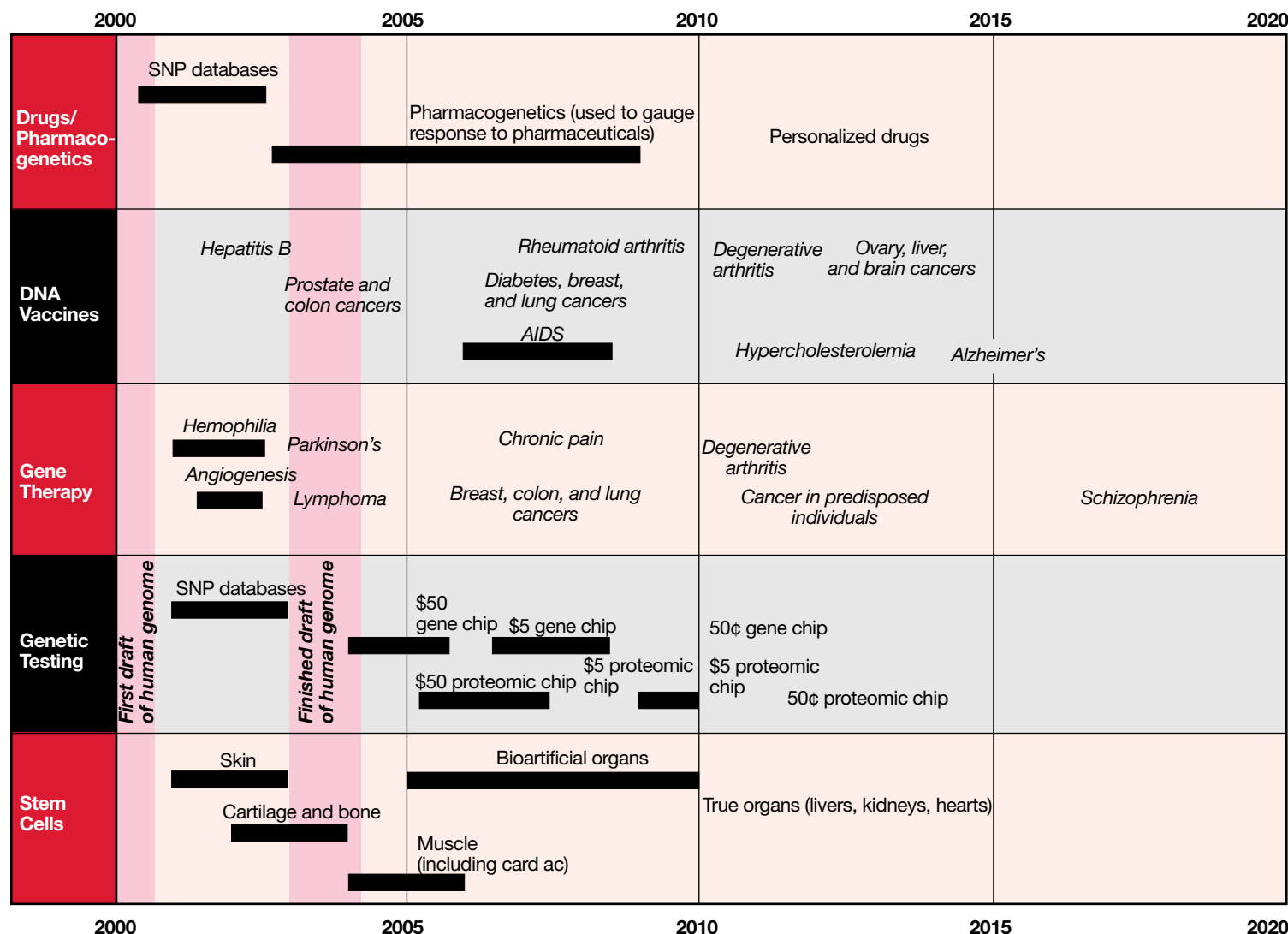
Institute Projects 20-Year Trajectory For Genetic Technology Development

Tracking Genetic Technology's Future

THIS TIMELINE WAS PREPARED by the **Institute For the Future (ITF)**, based in Menlo Park, California. ITF is an "independent, nonprofit research firm that specializes in cross-industry, long-term forecasting." It was founded in 1968. Its clients include Fortune 100 corporations as well as smaller companies.

In August 2000, ITF issued a special report titled *Genetics and Genomics: Transforming Health and Healthcare*. As part of this report, ITF included the timeline reproduced at right, which represented ITF's "best guess" at how genetic technology would evolve and find applications in medicine.

ITF acknowledged the difficulty of such predictions, saying "The following timeline of genomic developments reflects the influence that the availability of financing, the prevalence of ethical concerns, and the fragility of the technologies themselves may have on the speed at which these innovations are adopted by the industry, or by society as a whole." This table predicts that demand genetic testing will be driven by lower costs for "gene chips," and will begin to pick up as early as the year 2005.



Source: *Genetics and Genomics: Transforming Health and Healthcare*, August 2000, pages 28-29, Institute for the Future, Menlo Park, California.

redirect their healthcare dollars away from “all-risk” health insurance plans in favor of defined health services targeted at their individual needs.

EDITOR: You are saying that health insurance, as we know it today, will disappear because consumers will choose to spend their healthcare dollars in different ways. This seems consistent with your earlier prediction that healthcare will switch from “one-size-fits-all” to individualized health services.

CARLSON: Once genetic technologies mature, we will see a consumer movement unlike anything before, but it will only be available to those with the time and money to pursue it. “Retail eugenics” is a phrase that describes this process.

EDITOR: Eugenics is certainly a politically-loaded word.

CARLSON: Politically, yes. But eugenics simply describes the genetic differences in people. “Retail eugenics” is therefore a way of saying that a retail market for genetic-based human improvement will develop. Some consumers will pay for it and others will not.

EDITOR: I can see how this affects the health insurance industry as we’ve traditionally known it.

CARLSON: Most definitely. Today, health insurance is organized to take all that money from premiums and spread it out. The business model averages the costs of acute and episodic care across a large population. Everyone gets a little bit of something. You get a little bit of health services because your insurer treats you the same. To be insured by **Aetna, Cigna, Blue Cross** or any of the managed care plans brings very little

difference in the healthcare services covered by your policy. There may be minor price point differences in premiums, but the fundamental product is not any different.

EDITOR: And you see consumers changing that. Provide an example.

CARLSON: Take a family where two of the children are severely diabetic. Wouldn’t these parents prefer a health plan that is tailored to a family with two diabetic children? Why would those parents pay significant premium dollars into a traditional “all-risk” health insurance policy, knowing that someone else is getting most of the benefit? Once parents have access to a risk profile of themselves and their children, they want a health service tailored to their unique needs.

EDITOR: Which means they buy “individualized medicine,” just as you described earlier.

CARLSON: You can’t argue with that consumer logic. Today, all the national insurance plans are basically wholesalers. They buy healthcare services cheaply and hope that they can undercut their competitors’ prices by enough to win the business and still make a profit. But for the consumer, today’s Aetna products offer little differences over those of **Humana**, for example.



“‘Retail eugenics’ is therefore a way of saying that a retail market for genetic-based human improvement will develop. Some consumers will pay for it and others will not.”

EDITOR: You are making an important point here. Provide some additional insight into why consumers will divert their spending away from health insurance premiums.

CARLSON: Once a consumer knows what his or her risk profile is and understands his/her particular health needs, the notion of providing general, all-risk health insurance falls apart. Insurers will be unable to spread risk across a large number of people because those same people now want specific health services tailored to their personal health needs. For example, if they have high cholesterol and hypertension, they want a specialty health service that targets their condition and helps prevent them from having heart attacks, strokes, and the like.

EDITOR: In your view, this shift in how consumers buy today’s health insurance versus tomorrow’s targeted health services becomes an explosive point of conflict in coming years. How long before this happens?

CARLSON: Probably ten years. The managed care model, if it is not dead now, will be dead because of this coming change in consumer demand. Managed care firms are massive wholesalers, buying cheap and selling at a minimal mark-up. That’s all they do. Consumers who know, in advance, what specific disease is likely to afflict them, will want to spend the majority of their healthcare dollars on their specific problem. As they shift their spending away from traditional “all risk” health policies, they will have catastrophic insurance to back up unexpected health events.

EDITOR: You are again predicting that consumers will drive a major shift in how they spend their healthcare dollars.

CARLSON: The way things are structured now, this outcome appears inevitable.

EDITOR: Let’s move to your sixth point.

► Carlson’s Key Point #6 Impact of Genetics To Be Like “Reverse Alchemy”

CARLSON: I call this point “reverse alchemy.” In medieval times, the alchemist was an individual who tried to turn base elements into gold. Today, I consider genetic knowledge to be like gold. My concept of “reverse alchemy” involves taking this genetic gold and converting it into useful applications that are used extensively and frequently in common settings. However, our healthcare system, as structured today, is poorly equipped to convert genetic knowledge into applications helpful to patients.

EDITOR: There are two concepts inherent in your point. Let’s begin with the “reverse alchemy.”

CARLSON: Start with the “gold.” In my view, all the new knowledge flowing to us daily from those great scientists researching the human genome, is gold, it is valuable stuff. Alchemy involves converting a base element into gold. Reverse alchemy means this precious metal—all this new genetic knowledge—is pouring into a tin cup, where its value is suboptimized. To say it in another way, we don’t get the full benefits from the gold—the genetic

knowledge—that we should. Today’s healthcare delivery system is a tin cup. We are going to pour this new knowledge into a delivery system which does not know how to focus on prevention; does not know how to deliver a personalized product; is terrible at customer service; and lacks the cadre of professionals required to help patients work through their unique problems.

EDITOR: That’s profound! You are saying that today’s healthcare system lacks the capability to fully develop the potential of genetic knowledge. Where do you see the most critical mismatch between today’s capabilities and tomorrow’s needs?

CARLSON: The right healthcare professional for “genomics-based medicine” is someone who understands statistical modeling, is extremely fluent at discussing pros and cons, is adroit at using computer technology, and, most importantly, is a compassionate counselor. Does that sound like the typical physician? From the perspective of a corporate human resources director, our healthcare system is out of sync with the needs of a genomics-based medical system.



“The managed care model, if it is not dead now, will be dead because of this coming change in consumer demand.”

EDITOR: You are saying that many of today’s healthcare professionals do not possess the appropriate set of technical

and human skills that will be required in the coming “genetics-based” healthcare system. As you see it, the ability to analyze data and match that data to a patient’s particular needs will be a dominant skill set in this new type of medicine.

CARLSON: Yes. I also believe the knowledge we are discovering right now about the human genome will rank among civilization’s most important discoveries, like blood and anatomy by Harvey and Galen, dynamite by Nobel, and relativity by Einstein.

EDITOR: Now explain the tin cup analogy.

CARLSON: Picture the gold of our discoveries being poured into the tin cup of our existing healthcare system. We have early examples of how the debate on genetics is shaping up. Look at the struggles to introduce genetically-modified food. One foundation has funded research to develop “Golden Rice,” a genetically-modified strain of white rice with added genes that produces beta carotene, used by the body to create vitamin A. Worldwide, about 400 million people are at risk for vitamin A deficiency, of which 124 million are children. Use of Golden Rice in countries reliant on rice could help prevent the vitamin A deficiency which causes blindness in 500,000 children per year. But there are opposition groups blocking introduction of Golden Rice because it is “genetically-modified” and this runs contrary to their political agenda. Meanwhile, children in many parts of the world continue to suffer for lack of this essential vitamin in their diet.

EDITOR: That’s an interesting way to characterize the “tin cup” concept.

Segments of society are not ready to accept the benefits of genetic technology over fears about how the world might change as a result. The stem cell debate seems to mirror these issues.

CARLSON: Which is equally interesting. Those who are technically and clinically trained know that the stem cell line of discovery has little to do with genomics. It was started well before the sequencing of the genome. The science of stem cell development uses very little from the knowledge we are gaining from the sequencing of the genome. However, the debate about stem cell research is actually shaping the future regulatory and policy environment for genomics. As we’ve already seen, it’s a highly polarizing debate. We must realize that some people are piggy-backing on the stem cell debate as a way of making their own arguments that will also influence how our society eventually reacts to new technologies in human genetics.

EDITOR: Let me summarize your sixth point. You believe the growing body of genetic knowledge has all the value characteristics that gold does as a metal. But the reverse alchemy metaphor says that, as this “golden knowledge” pours into the tin cup of our existing healthcare system, it won’t deliver its full potential. That’s because our existing healthcare system is mismatched to the attributes required by a system of medicine organized around serving an individual patient’s unique needs.

CARLSON: Not a bad summary. Let me move to my seventh and final point. I call it “them” to “us.”

EDITOR: That’s intriguing. Please continue.

► Carlson’s Key Point #7 “Them” To “Us”

CARLSON: “Them” are the keepers of this new knowledge. “Us” are the patients, physicians, payers, and employers. The challenge is for “them” to pass this knowledge along to “us” so that we can use it right. I consider the dissemination of new knowledge into the healthcare system to be a serious problem.

EDITOR: Would an example of that be the difficulty of getting doctors to learn about new clinical procedures and apply them in their daily practice?

CARLSON: That’s one good example. Recently I was doing a workshop with a number of nationally-known physicians. In our discussion about how long it would take for physicians to learn and adopt new procedures based on genetic medicine, one doctor pointed at the scale of the challenge. He observed that it is real simple to treat people for ulcers the right way. But after 15 years of effort and education, widespread adoption and adherence is still much below what it should be.

EDITOR: So your point is that the dissemination of genetic-based knowledge will take an extraordinarily long time?

CARLSON: That is the crux of my “them” to “us” concept. Assume that our healthcare delivery system is dysfunctional in many important respects. It thus becomes a daunting challenge to get new knowledge in the hands of medical professionals in a way that allows them to put it into effective use.

EDITOR: In the context of your seven points, the “us to them” point seems complementary to the “reverse alchemy” point?

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“We are literally on the cusp of a massive change in the healthcare system no matter what any politicians think about it, no matter what any reformers think they want to do about it.”

CARLSON: That’s right. Because genetic knowledge is transformational, it will flow unevenly into the healthcare marketplace. It will be a daunting challenge to get today’s providers to learn, master, and begin to use new genetic-based technologies in their daily clinical practice.

EDITOR: Maybe the next step on our conversation is for you to try and tie all these concepts together. How do you summarize all of this?

CARLSON: I hope that my seven key points have helped you understand the deep changes which will be wrought upon both healthcare and society because of genetic knowledge. My purpose has been to give you some ideas, perhaps too many, that suggest and describe how extraordinary the journey of our healthcare system will be in coming years. Many physicians are frustrated about the shortcomings of our existing healthcare system. The good news is that genetics is coming and genetics will change the product. It will change what medicine does and make it more powerful.

EDITOR: But you believe there will be lots of struggle and conflict in this process, right?

CARLSON: No question. Yet, over the next 15 to 20 years, we will end up with

a healthcare system that is much more personalized, much more attentive to consumer needs, and capable of delivering high quality services. Also, believe it or not, over time it may be a lot less expensive.

EDITOR: In what ways?

CARLSON: Because we may eliminate the tariffs and infrastructure of the massive wholesalers of healthcare services. The system won’t need to pay the 25% to 30% that goes to the big managed care firms. They don’t serve a useful purpose in a system of personalized medicine.

EDITOR: Do you believe this change is unstoppable?

CARLSON: We are literally on the cusp of a massive change in the healthcare system no matter what any politicians think about it, no matter what any reformers think they want to do about it. The product is changing and medical care is changing in many of the ways I have already referenced. These changes erode the existing healthcare delivery models over time. Ineluctably they go away, leaving us, as individuals, for the first time with the ability to get the information we need to act in highly utilitarian ways for our own benefit.

EDITOR: One consistent theme in your comments is the preeminent role of the consumer in tomorrow’s healthcare system. Speak more to that please.

CARLSON: Remember that consumers will, over time and by accumulation, gain enough individualized information about themselves and their families to understand their risk and exposure to a variety of diseases and ailments related to aging. This creates a demand for individualized health ser-

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vices which the traditional “full risk” health insurance model cannot meet. If an individual is really healthy and knows his risk profile (of future disease) is minimal, why would he pay an insurance premium where he knows 80% of the dollars go to benefit someone else? Unless social policy is developed that justifies this difference, the competitive marketplace will offer this consumer “better” choices for how he spends his healthcare dollars.

EDITOR: You continually return to the theme of the consumer, armed with knowledge of his/her genetic risk profile, choosing to spend healthcare dollars in different ways than today.

CARLSON: My view is that consumerism will take off. The yield of genetic discoveries will make it possible for a consumer to buy, at retail, the specific health services that specifically to meet his or her individual needs.

EDITOR: This dovetails with your view that there exists a mismatch between changing consumer needs and today’s “human resources” in the healthcare system.

CARLSON: That’s right. As I said before, personnel within the healthcare system today are not trained, by and large, to work with consumers and patients who want to make those types of decisions. They are not adept at using statistical modeling, nor are many good communicators. Few healthcare professionals have any experience in counseling people about the pros and cons of possible choices and the long-term consequences of those choices. This means there is an extraordinary opportunity within some segment of healthcare to take the consumer movement seriously

and develop services to meet consumer needs.

EDITOR: Is this an opening for clinical laboratories? What is your opinion?

CARLSON: Two sectors of healthcare now undergoing the earliest impact of genetic-based medicine are diagnostic laboratories and pediatric and childrens’ hospitals. If you think about it, both of these sectors provide information and decision analysis to patients (consumers).

EDITOR: What about pharmacy?

CARLSON: Certainly pharmaceuticals and biotech is a big part of the early action because most of the therapeutic yield in the near term will be in pharmacogenomics. But it is diagnostic laboratories, childrens’ hospitals, and pharmacies where genetic-based technology will first make an impact.

EDITOR: How would you recommend that pathologists and laboratory directors pursue this opportunity?



“If there is a major take-away in this for pathologists and laboratory executives, it is that most consumers will want to know, through diagnostic testing, what the profile is for their future health, as well as that of their children.”

CARLSON: Within healthcare right now, the opportunity exists for laboratories to reconfigure the product they deliver to add information to basic testing services. Laboratories can help people make decisions about what they should or should not do.

EDITOR: However, this runs contrary to the traditional practice patterns of most pathologists. They perform tests on behalf of another physician's patients. For that reason, they have been reticent to communicate directly with those patients, out of concern that the referring physician would view that as interference.

CARLSON: Let me answer this point in another way. There are only 1,800 geneticists in the United States. That illustrates the gap between clinical professionals who understand genetic technology and consumers who want information and education about their personal situation. There is an enormous gap on the personnel side. This creates real opportunities for a laboratory, or any other provider, who can offer useful information not only to the consumer, but also to the health professionals on that consumer's care team.

EDITOR: Interesting. Your view is that diagnostic laboratories are well-positioned to be a value-added information resource.

CARLSON: Definitely. Individuals need information to better understand what their particular healthcare exposure is and how to deal with it. If they cannot get this from the Aetnas and Cignas who provide their health insurance, where will they get it from? They will go outside the traditional healthcare system. They are going to get the information they want.

EDITOR: That makes sense.

CARLSON: If there is a major take-away in this for pathologists and laboratory executives, it is that most consumers will want to know, through diagnostic testing, what the profile is

for their future health, as well as that of their children. Once they know that information, they will seek out a health services company that will help them manage their particular health risk.

EDITOR: And you don't think that traditional health insurers will provide those customized services. Who will?

CARLSON: These types of health services will be offered by companies like **Bally Total Fitness**. Bally is a billion-dollar corporation that owns and operates a national chain of 400+ gyms and provides fitness services to some 4 million. Companies like Bally will spot this opportunity in consumer health and, because they understand how to deliver services, they will develop individualized health services and offer them to interested consumers.

EDITOR: Coming back to clinical laboratories, in past years I've regularly predicted that new discoveries in genomics and proteomics will be good for the laboratory industry for a simple reason: before any physician can respond to a patient's unique health needs, that physicians must do a laboratory test to identify the genetic or proteomic profile of that patient. That places the laboratory squarely at the crossroads where genetic knowledge meets clinical practice. What's your advice for laboratories?

CARLSON: That's easy. Clinical laboratories and pathology groups are at the leading edge of the genetic revolution. By definition, it hits them squarely and puts them at the center of the action. However, to reap benefit from this situation, laboratories must: 1) embrace genetic-based healthcare technology; and, 2) adopt the new service model

required to provide clinicians and consumers those services. However, if the lab industry is resistant, I predict that much of this genetic technology will flow around laboratories and reach consumers through other channels. My point is that this revolution will not be stopped.

Advice for Laboratories

Carlson Offers Two Caveats

EDITOR: You are recommending that laboratories develop a strategic "comfort" with these technologies and the changes they will drive and be flexible and open to serving physicians and patients in non-traditional ways.

CARLSON: Precisely. Now two caveats. First, the full impact of genetic medicine is years away. Even so, laboratories are already among the first providers to see the practical applications of new genetic-based technology. That is why it is important for laboratories to incorporate effective responses today into their business strategies.

EDITOR: And the second caveat?

CARLSON: Second, in a business context, laboratories and pathology groups currently have a minimum of direct contact with patients and consumers. As these patients demand more information and services customized to their unique health needs, someone in the healthcare system will fill that need. Laboratories are perfectly positioned to be that information resource, but only if they change and develop more direct interaction with patients and consumers.

EDITOR: How will state laws that restrict consumer access to lab testing

and lab test results affect this opportunity?

CARLSON: That will not be an impediment. Such laws will be changed rapidly in response to consumer demand. Remember, people are willing to pay for the information that laboratories develop. From a business perspective, laboratories and pathology groups face a profound decision: will they be nothing more than an outsourcing solution for providers and health plans? Or will they become a direct-to-consumer business (while still providing services to physicians and payers)?

EDITOR: You pose a thorny question, particularly for hospital-based laboratories. Laboratories are already struggling to maintain adequate services in the face of declining reimbursement and pressures to reduce costs. You are asking them to shift strategic focus at a time when they are barely coping with the demands from clinicians in their community.

CARLSON: That's obviously true, but immediate action is not necessary. My advice and recommendation is that, because the types of transformations I speak of are years away, it is timely for pathologists and lab executives to begin thinking about the impact of genetic medicine now. This prepares them to deal with the consequences of the shift away from acute and episodic care provided in a standardized manner in favor of a healthcare system driven by consumers seeking individualized services tailored to their particular healthcare needs, with an emphasis on preventing or ameliorating health conditions to which they know they are predisposed.

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EDITOR: Returning to your earlier point, you believe laboratories will eventually face a strategic choice: continue as an outsourcing resource providing physicians with tests results, or develop a direct-to-consumer service channel. Can this be done in collaboration with the physicians on a patient's care team? Laboratories have always viewed themselves as a clinical resource for referring physicians.

CARLSON: I believe that would prove to be an effective approach. It's important to laboratories to become aware of how genetic knowledge will increasingly put consumers at the top of the healthcare pyramid. As that happens, laboratories will want and need to have strong relationships with consumers.

EDITOR: One laboratory company has already made that decision. Starting several years ago, **Quest Diagnostics Incorporated** made a major strategic decision to develop its relationship with consumers. It is building distribution and information channels directly to consumers. This summer it began offering consumers direct access to a specific menu of laboratory tests through 45 pharmacies operated by **CVS Corporation** in Ohio and Florida. (*See TDR, August 26, 2002.*) Quest Diagnostics also wants to brand itself with consumers, so when they think "lab test," they think Quest.

CARLSON: Strategically, I think Quest Diagnostics' consumer strategy is right on target. As consumers accumulate knowledge about the health profile of themselves and their children, they

will be looking for laboratories to perform tests and help them make decisions about their health.

EDITOR: Rick, during our interview you've not been shy about making some strong predictions about how genetic knowledge will revolutionize the American healthcare system. Any parting comments?

CARLSON: Just two. First, it is important for the lab administrators and pathologists who read THE DARK REPORT to understand that the forces I've discussed today will take several years to play out in the marketplace. There will be plenty of time to observe how these trends play out.

EDITOR: And your second?

CARLSON: Second is that leaders in all segments of our society are unprepared for the consequences that come from knowledge of the human genome. That means everyone is moving into an unknown future will relatively little forethought and even less consensus on how to respond to future events.

EDITOR: Thank you for a most enlightening look at how genetics knowledge will drive changes to our existing healthcare system.

CARLSON: You're welcome. Since meeting many laboratorians at the *Executive War College*, I've come to better appreciate the great opportunity laboratories and pathology groups have as genetic-based diagnostic tests move into the clinical marketplace. **TDR**

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