New Business Models for Breakthrough Growth

The Next-Generation Pharmaceutical Value Chain — An Arthur D. Little Industry Forum
About Arthur D. Little

Arthur D. Little is one of the world’s premier consulting firms, with offices and laboratories in 30 countries around the world. We use innovation to help leading organizations achieve rapid growth and breakthrough results. Arthur D. Little offers an unparalleled breadth of expertise in creating strategy, developing innovative technologies, managing organization to create lasting value, and helping companies implement e-business strategies to transform themselves in the new economy.

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Innovation and technologies with the power to disrupt markets and traditional patterns of competition are changing the face of healthcare. The winners in the future will be those companies that invent new business models to achieve breakthrough growth for healthcare products.

Arthur D. Little invited a group of leaders from biotechnology and pharmaceutical companies to gather in New York to explore "New Business Models for Breakthrough Growth: The Next-Generation Pharmaceutical Value Chain." Two days of working together produced thoughtful answers to questions like these: Can pharmaceutical companies make the technology shift necessary to maintain their competitive positions? Will biotech and emerging pharmaceutical companies remain independent and become new leaders in healthcare markets? Can truly collaborative alliances create win-win situations for the partners?

We value the insights of our industry colleagues who are achieving competitive advantage through new business models and alliance strategies. We thank them for their time and good counsel and we look forward to a continuing dialogue.
## The Participants

<table>
<thead>
<tr>
<th>Name</th>
<th>Title and Company</th>
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<tbody>
<tr>
<td>Jan A. Buck</td>
<td>Director, Global Healthcare Practice</td>
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<td>Arthur D. Little, Inc.</td>
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<td>Craig Carlson</td>
<td>Director, Corporate Development</td>
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<td>Arthur D. Little, Inc.</td>
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<td>Genzyme Corporation</td>
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<td>Healthcare Practice</td>
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<td>Arthur D. Little, Inc.</td>
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<td>Centocor, Inc.</td>
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<td>Richard F. Pops</td>
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<td>Alkermes, Inc.</td>
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<td>Kevin Rakin</td>
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<td>Genaissance Pharmaceuticals, Inc.</td>
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<td>Healthcare Corporation</td>
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<td>GelTex Pharmaceuticals, Inc.</td>
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<td>President (Retired), Johnson &amp; Johnson</td>
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<td>Development Corporation</td>
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<td>Officer Inverness Medical Technology, Inc.</td>
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Mastering Change—The Power of Innovation

Innovation and technologies with the power to disrupt markets and traditional patterns of competition are changing the healthcare industry. New therapies, next-generation drug discovery tools, and the unfolding promise of genomics have attracted enormous investments in biotech companies. Meanwhile, most large pharmaceutical companies, faced with patent expirations and R&D organizations unable to provide enough new products to sustain growth, are facing single-digit growth rates over the next five years. Here is the reality of today’s industry:

• The biotech companies need deep pockets and big-company market know-how to help with late-phase development and bring new products to market.

• The large pharmaceutical companies need innovative products to create a clear path to sustainable growth.

If mergers between the big and small, the old and new, aren’t always the answer—and frequently they are not, what is? What new business models have the greatest power to drive growth and create step-change improvements in value creation?

Companies able to exploit these new technologies—from innovation through product development and commercialization—will grow more rapidly and displace the leaders. It happened before and it is happening again. The keys to success include understanding the potential of revolutionary versus evolutionary technologies and knowing how to capture the value of that innovation, at the research level and all the way through an organization to strategy and operations. The winners will be those companies that use this knowledge to invent new business models to achieve breakthrough growth for healthcare products.

Such were the observations of decision-makers from biotech firms, pharmaceutical companies, and healthcare provider organizations who met for two days with Arthur D. Little (ADL) health industry specialists at the company’s Innovation for Value Creation Forum in New York City.
The Changing Face of Healthcare

The economics have changed.

While the Forum participants approached the challenge of disruptive changes in their industry from where they sat—biotech, big pharma, or medical devices—they agreed that the fundamental healthcare economics that drive the traditional business model for the pharmaceutical industry are changing. Vicki Sato, President of Vertex Pharmaceuticals, explained: “All the value-added economics of pharma have traditionally come at the end of the value chain, because the odds have been so bad that a compound will actually make it. Companies get discounted all the way through, until they make it to the end, because nobody believes they’re actually going to make it to the end. If technology can have a significant impact on the R&D process earlier on, is it possible to build a business model in which the point of profitability, if not shifting sharply, can at least move further from that end point?”

In fact, can companies actually grow at a rate and pace that allows them to capture value from genuine technological innovation as well as genuine product development and commercialization? A major part of the problem is big pharma’s inability to bring new technologies and new therapies to market at the rate and quality that shareholders have come to expect from them. “This,” said Pam McNamara, “is one of the seismic shifts under way in the industry.” McNamara, who hosted the Forum, is a Vice President and Managing Director of ADL’s Global Healthcare Practice. “Innovation and productivity problems in research and development, as well as the growing complexity of drug research, have created these challenges. Are we looking at a future of more blockbusters, or a future of more personalized medicine made possible by advances in genomics? Another problem is big pharma’s ability to screen what’s coming, what’s attractive—their ability to capture potential value.”

To capture value, companies must not only recognize the potential of a new technology or innovation, but also create the organizational screens to capture it. As Victor Schmitt,
President of Venture Management at Baxter Healthcare Corporation, noted: “Almost by definition, a disruptive technology will fail to get picked up by all of the traditional screens that a company uses to evaluate where to invest. We are really trying to understand how you figure out what to do with the most innovative technologies, the ones we typically call disruptive. It’s not an easy problem.”

This has been particularly true of genetic variation. It was first viewed as an innovation that would not play a significant role. “People thought it would make markets smaller, as each new discovery would be tailored to specific groups or individuals,” said Kevin Rakin, President and CFO at Genaissance Pharmaceuticals. “Now it is seen as the very future of medicine—the ultimate in disruptive innovations.”

**Disruptive technologies transform markets.**

The history of business is replete with examples of management that made gradual, evolutionary changes to sustain their companies—only to lose the war to more disruptive, revolutionary technology. Witness the DEC mini-computer vs. the PC, integrated steel makers vs. mini-mills, and RCA and others vs. the Sony transistor radio. Truly disruptive technology changes the fundamental value networks in an industry and brings in nimble new players. Witness what is happening in the healthcare industry.

Advances in mapping and sequencing the human genome, along with continuing breakthroughs in proteomics and cell biology, are having a revolutionary impact on healthcare. These innovations have given us a greater understanding of disease and medical conditions—and how we might treat or prevent those conditions. They have also turned the healthcare industry on its head. “By definition,” said Joel Yanowitz, the Forum moderator, “disruptive technologies transform markets and change the rules of the game for entire industries.”
New Sources of Innovation

In the United States, total pharmaceutical sales grew at 14 percent a year through most of the 1990s, with most of the major pharma companies experiencing double-digit growth. Now that growth is slowing, only exceptional companies are posting compound annual growth above 10 percent. A tidal wave of megamergers has been the response to slow growth among many companies. However, this has only made the absolute size of the growth gap bigger as most of these companies continue to have insufficient products in the R&D pipeline, coupled with unprecedented patent expirations in the next few years.

At the other end of the size spectrum, emerging biotech and new technology companies are being rewarded by financial markets for the expectation of dramatic future revenue growth. These companies are the new players that revolutionary innovation attracts. In 2000, $37 billion was invested in the biotech industry.* According to Eric Roberts, Managing Director and co-head of Global Healthcare at Lehman Brothers, this unprecedented wave of funding marks a turning point. The current boom in financing looks ahead toward innovative therapies that are reaching proof of concept, as well as the next generation of drug discovery tools and the promise of genomics.

Currently, more than 350 biotech compounds are in late-stage clinical trials and over 90 biotech products are on the market, most launched in the past five years. Of the 1,600 new technology companies in the United States and hundreds in Europe, only a few dozen have actually launched products. But their success so far, said Louise Firth, Vice President with ADL’s Global Healthcare Practice, is the result of focus and innovation rather than incremental improvement. “These companies are concentrating on developing promising and innovative therapies to address health conditions not adequately treated with existing therapies. For example, Esperion was formed in 1998 to develop a novel class of drugs designed to treat both acute and chronic atherosclerotic disease based on HDL. Major pharmaceutical companies have focused on developing statins, which limit the progression of the disease by lowering levels of LDL, but statins generally do not reduce atherosclerosis. So Esperion

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is focusing on a therapeutic approach below the radar screen of major pharma that could lead to a breakthrough in the treatment of cardiovascular disease while major pharma companies are trying to beat Lipitor®. Genzyme is an example of a biotech company that has grown by focusing on innovative approaches targeting diseases that have few, if any, effective therapy options and patient populations too small to be of interest to major pharmaceutical companies pursuing mass markets.

*The market rewards the expectation of success.*

How much can, or should, the market reward innovative companies for a promising future—long before the profits start to flow? The industry is awash in extremes. Richard Pops, the CEO of Alkermes, observed: “There are certain biotechnology companies with multibillion-dollar valuations now that are not profitable companies, that do not have significant drugs in late stages of development, that don’t...
have fully worked-out development engines. That's more than just a passing concern.” GelTex Pharmaceuticals President and CEO Mark Skaletsky, agreed. “Millennium’s market cap was as high as $18 billion in 2000. That puts them right behind Genentech. All Millennium has to do is hiccup and I think we’ll see the world begin to tumble in this industry in terms of valuations. It’s pretty frightening to think of the impact that could have on all of our companies.”

“I agree,” added Richard Douglas, Senior Vice President, Corporate Development, for Genzyme Corporation. “If you are a profitable company, you are valued on your growth rate and earnings, not your innovation. And yet the genomics world, which is getting valued on innovation, has this long timeframe for innovation. Is the marketplace willing to wait six years for a Millennium to create a product that makes money? If the market doesn’t wait, and all the elephants stampede for the door, it’s going to end up smashing a lot of us.”

“In the old days,” said Jan Buck, who heads up ADL’s Health Sciences Fund, “meaning 5 to 10 years ago, a $500 million deal led people to conclude that there was something big going on. Now, if there is evidence that some of these high-valuation research programs aren’t productive, and word gets out to the Street, that may be when some of this stuff starts to unravel. I think the expectation is huge.”

The premium for innovation is, however, much more than just improved market capitalization. There’s also a creativity premium, the leverage that a little bit of ingenuity provides in terms of momentum and growth. According to Ron Zwanziger, Founder, Chairman, and CEO of Inverness Medical Technology, innovative companies should not worry about how high or low the Millenniums are valued. “Our job is to focus on technologies where we can open up a gap between ourselves and either big pharma or a big biotech firm. What investors need to see today are opportunities to invest where they believe the gap is maximized. Where we will be in 10 years depends on our own ability to open that gap.”
That gap, a tangible measure of innovation, explains why some large pharmaceutical companies have taken equity positions in biotech companies. “It’s not necessarily to get a financial return,” Barry Ross, CEO and Scientific Director of Affymax, explained. “It’s also a means of getting a technology return. And it’s the technology return that drives the pharma corporate strategy. If there is a financial return through an equity holding, that’s all very well. But I don’t think that has ever driven the relationship.”

“If,” said Genaissance’s Kevin Rakin, “large pharma companies can’t grow at a rate the market wants, then innovation has to grow somewhere else. Why shouldn’t 90 percent of the value go to innovation?”

Capturing the Premium From Innovation

Some of the more successful new technology companies have become full-function pharmaceutical companies, and many of the emerging technology companies aspire to do the same. As a result, straight licensing deals between large pharmaceutical firms and some of the new technology companies are becoming less feasible. However, all but a few of the newcomers that have launched products have had to align with larger pharmaceutical companies to carry out the expensive Phase III development and downstream marketing and commercialization. In these cases, biotech and large pharmaceutical companies have come together in new ways to take advantage of their respective strengths.

*Biotech innovates, big pharma commercializes.*

Vertex Pharmaceuticals, the drug discovery company founded in 1989, and pharmaceutical giant Novartis have recently entered an alliance in which Vertex will do the early drug discovery and development, and Novartis will handle the late-stage clinical development and commercialization. The companies have formed a joint development committee.
and Vertex has the option to co-promote in the United States and the European Union. “We felt,” says Vertex’s Vicki Sato, “that the global reach and financial resources of Novartis would add considerable value to what we were doing at Vertex. And Novartis felt that the innovation coming from our research engine at Vertex was different than anything they could build in-house. So it’s an interesting experiment, and speaks to both innovation and capturing the value of that innovation in a different kind of model. And that’s an important issue for us.”

The Forum participants agreed that some new technology companies want to acquire late-stage development, marketing, and sales know-how from big pharma and, for the most part, are willing to share bottom-line profits to get it. But how do healthcare leaders on both sides of this new equation find partners that represent a true exchange of value?

Recently retired head of J&J Development Corporation James Utaski, now with Whitestone Capital, said he was struck by the dichotomy of innovation versus commercialization. The capital markets, he said, have two poles. “One pole is what large pharma is good at, which is commercialization, bringing something around the world. It’s pretty complicated and expensive to set up an operation in China, an operation in Poland, an operation in East Asia… learning to deal with all of the regulatory aspects of Europe, and also field a 3,000-person sales force in the United States.

“So what pharma companies do, and what they do well, and where their value creation is excellent, is commercialization and, among the better companies, even Phase II and III development. Big pharma knows how to sell, how to present data, and how to get a drug through the regulatory system and into the world market. Where big companies are not very good—and this is where the dichotomy is most visible—is in the innovation process: the early discovery, the early incentives, creating the staff, the talent, the observations, and the innovation that will eventually change healthcare, whether it be new pharmaceuticals, new biotech proteins, or new devices.”
With innovation best created in small companies, and commercialization best done in large, global organizations, the stage is set for a contest over how to divide the returns on these capabilities. No longer are small companies content to just license away products. They want to share in the profits as well as learn marketing and sales skills. Arthur D. Little sees the resolution of this tension as the most pressing issue facing the industry over the next few years. Innovative solutions achieve the breakthrough growth that the investment community demands.

Genaissance, for example, a company of 130 people, has just published the first study correlating genomic variation to
drug response, and has raised $150 million in fresh capital this year. The firm is in a position to influence a totally new market for genomics, called pharmacogenomics, which is focused on drug development and matching patients with the drug that is best for them—not on drug discovery alone.

The question now, in terms of business model and strategy execution, is: how do smaller companies get these new technologies accepted? “What kinds of partnerships do you form,” Genaissance’s Rakin asked, “given the capital we’ve been able to raise? Traditionally, biotech companies, and genomics in particular, had to rely on pharma partnerships for long-term value. Now we are looking at ways to change that value creation.”

One of the ways in which value creation is changing, Rakin explained, can be seen in the application of genomics. New chemical entities, the key component of drug patents, will become circumscribed by genetic variation issues, which in turn become part of the patent state of new drugs. “If you accept that genomic variation is important in terms of value creation for the drugs of tomorrow, then clearly there are significant assets here. And as I said, we’ve been able to raise significant capital on our own to fund this new future,” Rakin said.

Using New Knowledge to Build New Models

How are the industry players responding to the challenges of finding innovative products, bringing them successfully to market, and finding a path to sustainable growth and returns? The Forum participants agreed that the launch or transformation of any set of revolutionary business models demands that players do one or more of the following:

• Form alliances relentlessly
• Leverage other companies
• Re-examine big pharma partnerships
• Open the pipeline for blockbusters
• Exploit big pharma advantages
Form alliances relentlessly

“The mergers we’ve seen in the last several years are certainly one response,” said ADL’s Pam McNamara. “Some companies, such as Johnson & Johnson and Pharmacia, have picked up smaller companies, such as Centocor and Sugen. And we’ve also seen a flurry of alliances across the spectrum from discovery and development to demand creation and order fulfillment. The Vertex and Novartis example is a good one. What makes the successful ones we’ve seen work? The key factors we’ve observed include:

• A clear and specific alignment of business objectives for the alliance or joint venture partners

• Dedicated senior management oversight, and dedicated teams at the operating level

• Balanced and flexible agreements—balanced in that the alliance is well aligned to both parties’ objectives and flexible enough to evolve and change”

Leverage other companies

Will big pharma companies that are extroverts—those that leverage their resources by forming multiple alliances across the value chain—succeed? Will new technology companies that form truly collaborative alliances in their focus area—or to complete their value chains—succeed?

Vertex is working toward answers to these questions right now as it works its research and early development partnership with Novartis. The Forum participants generally agreed that combinations, whether joint ventures or ongoing alliances, do hold the key to success, at least success on a faster track than most companies see going it alone.

“The environment is forcing us to be more proactive,” said David Holveck, Company Group Chairman of Centocor, Inc. “We have to be more cost-conscious. So I do think big pharma is going to have to find ways to focus down and get
it done. It’s a transformation. The same way public utilities have had to transform themselves into a more competitive industry.”

David Gury, Chairman, President, and CEO of Nabi, saw it the same way. “I think that big pharma companies have growth rates that require them to have a better hit rate. So if you’re going to hit 1 out of 10, then you’ve got to get more times at bat.”

Craig Carlson, Director of Corporate Development at ADL, sees networks of companies and capabilities forming around pieces of the value chain, such as research and development, launching and commercializing, and distribution and customer access. “We see these,” he said, “as compelling networks with exciting possibilities.”

Re-examine big pharma partnerships

Beyond who can or cannot raise capital, part of the partnership tension between large pharma and the biotechs hinges on expectations. Alkermes’ Richard Pops: “I believe that the stated growth rate objectives for the megacompanies are difficult to sustain over the long term. That doesn’t mean that the combinations don’t make sense in the short term. If we combine two large companies, we can almost guarantee improved financial performance for a number of quarters, based largely on cost reductions. But I don’t believe that in the end the growth rates are sustainable off that new expanded revenue base.” To this point, when megamergers occur, the new company spends so much time on integration and cost reduction, it’s unable to maintain market share.

Moreover, though contrary to current popular belief, Pops sees partnering with big pharma even more difficult than it has been in the past. “Companies,” he said, “are taking longer to approve partnership terms—even when the terms have already been negotiated and approved months earlier. I think this is indicative of a general phenomenon that you see with many large companies. In trying to make themselves more agile, they try to codify best practices for dealing with
Addressing the Critical Questions

Healthcare companies face the challenge of dealing with a radical shift in the technology base for product innovation at the same time the Internet and other communications technologies are reshaping the world. To address the product technology base, pharmaceutical companies have significantly increased R&D spending as a percentage of sales, with no corresponding improvement in the rate of introduction of new chemical entities or the strength of their product pipelines (see figure). Most major pharmaceutical and medical products companies are facing single-digit sales growth for the next five years. At the other end of the spectrum, the biotech and emerging technology companies have innovative products in development but generally lack the skills and resources to successfully commercialize. Each group is facing tough questions.

How do you plan to:

• Improve the success rate of products in development?...on a sustainable basis?

• Shape and drive partnerships and alliances to access new technology?...or to achieve scale and scope?

• Build the right business models to make alliances succeed?

• Exploit the Internet and other converging digital technologies—including mobile and wireless communications and networking—to help run your business on a more global scale and to commercialize your products?

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Pharmaceutical Industry R&D Productivity

While R&D spending escalated through the 1990s, there was no corresponding increase in R&D output, as measured by NCEs.

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Source: ADL Estimates
innovation. And anything that becomes codified becomes unwieldy pretty quickly.”

Small but well-financed companies with development resources have the unique advantage of sitting everyone down at the same table where they can put an entire program together, including milestones, royalties, development funds, technology validation—all of the hard and soft business decisions that companies need to make. Not exploiting this advantage over large pharmaceutical companies, according to Pops, is a very big mistake.

Alkermes’ experience with big pharma has been generally positive, however. And its lessons learned have value for other small companies. Alkermes used its drug delivery technologies and partnerships with major pharmaceutical companies to learn how to run clinical trials, scale-up technologies, build manufacturing plants, and create quality organizations. Now, Alkermes is developing its own products and, according to Pops, the firm has a road map for delivering new products over the next several years.

Open the pipeline for blockbusters

The most recently launched blockbuster drugs have these things in common:

- Deliberate positioning—well thought-out and designed approaches to achieve differentiation, accelerate approval, gain leadership through preemptive development—all as part of an overall life-cycle management program

- Speed—accelerated clinical development that minimizes the time from approval to launch and the time needed to prepare for commercialization

- Megalaunch—applying marketing and sales resources in the launch year that exceed peak-year values for earlier products

- Global sales maximization—launching in many markets, as quickly as possible
For a mass-marketed product, blockbuster success requires a sales force effort in year one in excess of 2 million physician calls in the United States alone, and a total life-cycle development cost between $750 million and $1 billion. Looking ahead, price controls or other methods of increasing competition within drug classes will make this situation costlier still, making it even more difficult to justify this level of investment.

Is the blockbuster bar too high for second-tier pharmaceutical companies and even top-tier companies not well-established in a therapy area? Jay Pieper is Vice President of Corporate Development and Treasury Affairs at Partners HealthCare Systems. “That was a concern I had coming into the Forum. I’m not so concerned now. I think that there is a substantial amount of activity going on and will continue to go on sort of underneath big pharma to fuel the next generation of breakthrough products. Good ideas are everywhere, we just need to be open to them and looking for them.”

Exploit big pharma advantages

One advantage large companies have in this period of extraordinary change is the ability to wait and see. It’s a strategy that some Forum participants called “waiting in the grass.” A large company, when it sees a new technology that it wants, can forward-integrate it, put its resources behind it, scale it and commercialize it. There are certainly companies that have innovative products but not the means to compete economically in the marketplace. David Holveck called this situation “a matter of balance.”

The large pharmaceutical companies will find themselves behind the curve in many development areas by as much as a year or two. But it may not matter, as long as they recognize what’s going on and can jump in when the risks have reached a point where they can see a positive return on their investment.
The traditional value chain will disaggregate and reaggregate, forming new business models. Traditional pharmaceutical companies will continue to excel at mass-market commercialization and marketing but will not be able to sustain sufficient innovation internally. Also, biotech and new technology companies will continue to lead in technology innovation—genomics, new discovery platforms, and new therapies—but will not be able to effectively reach mass markets on their own.

Looking Ahead...”No Bad Scenarios”

After participants examined alternative healthcare scenarios for the future, Nabi’s David Gury had this to offer: “I am struck by the fact that we couldn’t come up with a bad
The combination of computer technology, handheld devices, voice communications, and wireless access to the Web has tremendous implications for transforming healthcare delivery. As for the information value of the Internet, patients are often as informed (and in some cases even better informed) than their physicians regarding their disease state because of their ability to access medical literature and learn from other patients. Moreover, healthcare providers can use the Internet to address individual patient needs in cost-effective ways not previously possible. Over time, this will move treatment of diseases that are now managed by specialist physicians toward primary care.

The Internet itself is an evolving disruptive technology that continues to create totally new sets of business models. Much more than a communications system, it has evolved into a low-cost platform for interconnecting business systems. Previously, that required having an information technology consultant come in and develop a hundred-million-dollar project over a five-year period to totally rebuild existing information systems. Such a situation can now be better handled in a more tailored way at very little cost—depending on what systems you have—with an integrated Internet solution. ADL recently entered into a strategic alliance with CoCreate Software, a leading designer of collaborative software solutions. This Web-based collaboration will help companies reduce development costs and time to market.

This is a fascinating time. A time of enormous change. Healthcare businesses need to take advantage of disruptive technologies, to look at future business models that will be enabled by all of these capabilities. Most sectors will redefine the entire value chain to better link all the segments, from individual consumers backward, to make it more cost-effective across the entire spectrum of healthcare.

scenario for the industry—and I can visualize some that are a lot worse than what we considered here. It is encouraging to see that significant opportunities remain in how we deal with healthcare issues and how we provide solutions that don’t exist today. Even if we consolidated all the public biotech companies and the thousand or so private companies, there would be more that would come along. There would be new formations with new capital and new ideas that would take their place. You can’t come up with a doom-and-gloom scenario. Some will be a lot more productive than others, but I think it’s pretty exciting.”

Regardless of the way the U.S. economy and healthcare spending are managed in the next decade, the Forum
participants, in the course of their two days together, found agreement on several points and potential outcomes:

- The bar will be higher for innovation but true innovation will be rewarded.
- Many of the new technologies are disruptive: they will transform markets and redefine product categories. Genomics is a prime example.
- Therapies of the future will be more targeted to specific sub-segments and become more personalized.
- Pharmacogenomics will create genetic prescriptions.
- Traditional pharma may essentially restructure to improve shareholder value and access to capital markets.
- Broader, more collaborative alliances will be pervasive—among biotech/new technology firms as well as with traditional pharma—creating new business models.

**Innovation as a source of value**

In Arthur D. Little's work with healthcare companies around the world, we’re seeing an expanded definition of innovation at work in the creation of new value. The industry leaders at the Forum in New York who took the time to share their experience and counsel were also working with this enlarged understanding of innovation. Clearly at this Forum, and in the global marketplace at large, innovation means R&D, but it means much more. For innovation to drive growth and transform industries and markets, wise managers think in terms of strategic innovation and operational and performance innovation as well as product innovation. It is at that intersection of strategy and innovation that new and established healthcare companies will find and launch new models to harvest growth.

In a period of blinding acceleration of knowledge transfer, the necessity to create these new models—new kinds of value chains—is critical to the healthcare industry. Not only must the creation of sustainable streams of new compounds be managed innovatively, new business models must be invented and reinvented continuously—to meet regulatory hurdles, to contend in expanding and changing markets, and to satisfy the expectations of patients and doctors as well as shareholders.