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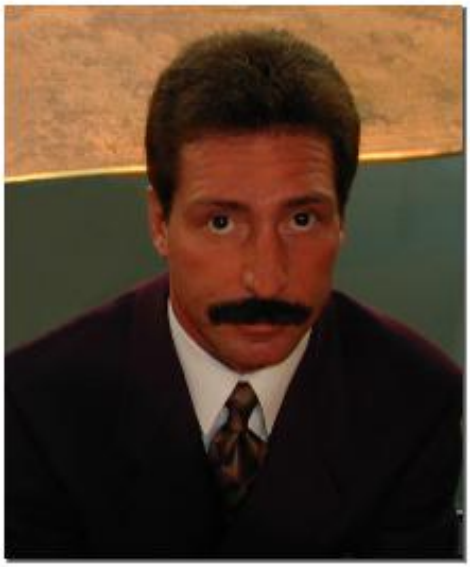

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Merged Platforms: Bargain or Breaking Point?

CAP Today, August 2002 Cover Story

Anne Paxton

Bolstered by the consolidation wave, laboratories with some of the country's largest healthcare systems continue to aggressively standardize more platforms–not only capitalizing on industry competition to get the best price, but also sometimes finding new ways to share the risk of these large instrument acquisitions with the vendor.

Could these tactics backfire?

Some industry analysts warn that laboratories are relying too heavily on "vendor squeeze", as they put it, to improve their lab operating costs. "If laboratorians drive prices and margins down below the levels of other areas of technical medicine, innovation will dry up," says business consultant Robert Bauer, president of CaseBauer in Irving, Texas.

While laboratories are making short-term gains, Bauer believes that lower margins will drive more diagnostics industry consolidation and starve research and development. "It's pretty clear that prices can't continue to go down and innovation to go up. And laboratorians aren't really comprehending that by the time they feel the effects, it won't be a reversible situation."

For their part, however, laboratory directors with large systems can point to millions of dollars in savings on laboratory costs as a result of consolidation. In negotiating contracts with instrument vendors, size remains a powerful weapon for laboratories to bring to the table.

North Shore Long Island Jewish Health Care System is a notable example. With $3.5 billion in overall revenue per year, it is one of the five biggest nonprofit hospital systems in the country– and one of the few not losing money.

"It's one system that actually makes a profit, and every vendor wants in," says Thomas M. Sodeman, MD, Chairman of Laboratory Medicine for North Shore LIJ, located in Lake Success, NY. "When you have 32 blood gas machines scattered across the system and two or three vendors in that market, that gives you a lot of buying power. It becomes pretty competitive to acquire this contract." Because of the range of its laboratory services– which include supporting acute-care hospitals, serving as a reference facility, performing nursing home and physician office testing, and conducting clinical trial laboratory testing–North Shore requires a wide range of instruments.

"Ninety-eight percent of the laboratory work ordered here gets done in the system," Dr. Sodeman says. "When you get into the immunoassay equipment, we have at least one of almost every product out there, and the reason is the menus are all different and in order to get the full depth of menu you end up having to get all these different analyzers."

Negotiating clout isn't the only advantage of North Shore's size, Dr. Sodeman notes. Since there are 18 hospitals in the North Shore LIJ network, "we also have the ability to experiment and we can bring in different instruments at different sites, with the idea of taking a look at them for a period of time, maybe two or three years, and getting a good feel for whether we want to sustain a relationship and sign a contract for three years." For example, the system recently placed two Olympus 2700s on a trial basis in an 850-bed tertiary and pediatric hospital.

It makes good sense to have standardized equipment across an entire system, because you can cut a better deal, quality control is more consistent, and there's no problem with lack of correlation, Dr. Sodeman points out. But he cautions that there are disadvantages too. "The last system I was in, we had all one company's equipment everywhere, and when we had a chemistry problem, we were up a creek."

"There are always a couple of chemistries on every system that don't seem to correlate with what else you're running," he continues. "That's true for all manufacturers, and that's why some people go with one line of products across the whole system." The trouble is that North Shore services 5,400 beds, and like a passenger jet, it needs redundancy in the system

to ensure that any single breakdown doesn't grind the system to a halt.

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"If we were to have the same chemistry analyzer everywhere and something goes wrong with the reagents, or something happens with that product–it could be the calibrators or a variety of things–then the whole system goes down," Dr. Sodeman says. "So what we do is maintain a set of equipment at the core, and another set out in the hospitals, so for main chemistry and main hematology we can always back up to the other resource."

ACL, the joint operating agreement between Illinois-based Advocate Health Care and Aurora Health System in Milwaukee, Wis., is comparable in size to North Shore LIJ. It is just now finalizing a contract for hematology equipment with Abbott Diagnostics, following an extensive and highly structured acquisition process.

Cheryl Vance, ACL's vice president of Illinois operations, says having 23 hospitals across two states to some extent puts ACL in the driver's seat. "Because ACL is such a large organization, the vendors are very interested in getting our business. They've been very willing to be aggressive in meeting our time lines with request-for-proposal information and in the pricing they've presented."

That has given ACL room to push for more favorable contract provisions, she adds–ones that ask the vendor to share some of the risk of the acquisition. "What we have done traditionally is either purchase capital equipment and pay for reagents, or we've done leases," she explains. "We are now working with vendors to do a cost-per-reportable arrangement."

Under this type of agreement, says ACL general manager Jay Schamberg, MD, "We don't pay for installation, maintenance, and reagents separately. We contract with the vendor to supply us with the capital and disposables and maintenance to pay them on the basis of reportable tests. That puts them at risk if the instrument doesn't work well and requires excessive maintenance or repeat tests."

Since this means the institution pays a fixed cost per reported test, Vance notes, "when we do a CBC that's reported back on a patient, we know we're paying that dollar amount, and there aren't hidden costs for duplicates for proficiency testing, controls, and so on."

Cost-per-reportable contracts are not common yet in the diagnostics industry, Dr.Schamberg notes. " Laboratories have always been interested in it, but vendors have shied away because there are no hidden costs" such as computer paper, added maintenance, or "laptops you didn't know you had to buy".

But sharing the risk is not something that manufacturers are eager to engage in. "We find that because of our size we seem to be able to get very good pricing," Dr. Schamberg says."Where we have some issues is in terms. There are certain things our systems want in protections that not all vendors are willing to do. If the instrument malfunctions and causes a patient damage, is the vendor willing to be responsible for any damage that can be attributed to their instrumentation? Are they willing to assume some liability? There are a couple of instances where we haven't 'gotten to yes' because of terms like these."

Vendors often want to talk about being "partners" with the laboratory, Dr. Schamberg adds. "To me a partner is somebody who shares substantial risk. We've found, when we get down to really saying, Are we going to share the risk, there's suddenly a little less enthusiasm. Some are willing to do it if we standardize on all of their platforms. But we don't think a single vendor can [cover all of our needs]."

Although the Abbott Diagnostics contract is far more significant, ACL actually has a cost-per-reportable arrangement with a couple of vendors already. Says Vance, "Diagnostica Stago was one of the first organizations we approached to do cost-per-reportable pricing for one of their coagulation tests, but it is relatively low-volume." Two years into the contract, ACL has found it to be working well and is now in the clinical evaluation process to reach a new systemwide coagulation contract by theend of the year, to be followed by contracts for chemistry and immunochemistry.

Vance feels that this risk-sharing creates a stronger partnership with the vendor because both parties have a direct interest in maximizing the equipment's potential. For example, "if the equipment is set up to do automated differentials with a linearity down to zero, and that was what was factored in the pricing, we need to work with our clinical people so they accept that they should not be doing manual differentials or to be running testing in duplicate when it's not appropriate in today's market."

Sutter Health, the largest not-for-profit integrated delivery network in the country, has found that standardization presents unique challenges. While Sutter has not written risk-sharing arrangements into its laboratory contracts, one of the IDN's strategies as it seeks to reduce the number of contracts with different vendors has been to make more gradual transitions.

"Especially as large as we are, one of the significant issues in contract management is to really try to get one vendor able to adjust to the different needs of our affiliates. It's very difficult to come up with a single-vendor solution," says Robert Stephens, a contracts analyst with Sutter's corporate offices in Sacramento, Calif. "If we were all strictly acute-care hospitals or all outpatient facilities, it would be much easier."

To ease the transition process, particularly with regard to capital expenditures, the vendor that Sutter chose recently for its coagulation standardization "is not pushing us directly for an analyzer conversion right off the top," he says. "They're saying

rather than convert X number of analyzers in the next three years, we'll replace analyzers with the vendor's brand just as they come up for replacement over the next five years."

As Sutter looks toward potentially standardizing immunoassay and chemistry in the next few years, the longstanding relationships the various affiliates and vendors have developed pose hurdles. "The issue is not really platform-specific; it's just that who the affiliates have been working with goes a long way in determining who they will be comfortable dealing with in the future. There's no perfect analyzer, by any stretch. But most of the affiliates have been working with their vendors for years; they know the ins and outs of a platform–they have adapted to or accepted its shortcomings and know how to work around them."

Laboratories make far fewer demands on administrators than do other hospital clinical departments, Bauer contends. "We've had administrators tell us that on a dollar basis, the laboratory is the least complicated, controversial, and aggressive part of the institution they deal with. If you look at other areas, those departments are coming to administrators with demands and justifications for making additional expenditures in order to improve. They're actually selling them on investments that will improve medicine, decrease downstream costs, and save manpower or save on supplies over aperiod of time."

"But laboratories almost always come to the administration with noncontroversialproposals that are cost-neutral or cost-favorable. 'This doesn't cost anything–is itokay?'" Rarely will they sell administration on labor savings, better medicine, or lower downstream costs. "As opposed to radiology, for example, which might say we need a million-dollar investment to improve services and reduce expenditures over the next five years," Bauer says.

The laboratory budget numbers are high, he says, but in terms of capital expenditures, they're not high at all. "They're not competing for the capital equipment dollar or selling the value of innovation; they are avoiding that challenge," he says.

In periodic surveys of hospital administrators over the last decade, CaseBauer has found that administrators have gained little awareness of laboratory vendors or products."Most administrators consider the laboratory as something that almost runs on autopilot; they're rarely challenged to make a difficult decision or immerse themselves in alaboratory product analysis."

This pattern may explain, for example, why total laboratory automation hasn't done as well as might have been expected, he says. "Sure, in small operations the equipment doesn't cost-justify. But considering the degree of laboratory consolidation and the size of some laboratories, it's clear the market is undersaturated or not at its potential," hesays. "But laboratory automa-tion is one area where you have no choice but to go to the administration and sell an investment, and there just aren't that many laboratories that are skilled or interested in doing that."

Bauer says the physical consolidation of laboratories may have stabilized, if not peaked, because laboratories are asking at what point the tradeoff is optimized. "I'm not sure more consolidation is going to outweigh the benefits of reduced turnaround time," hesays. "Lots of proposals on the table for more laboratory consolidation have actually fallen through. We've run into laboratories that have decoupled or loosened up their consolidation strategy. For more highly automated processes like clinical chemistry and immunochemistry, once you've thinned your management, what happens when you consolidate? You just end up putting more instruments in one location with the same manpower requirement. How much economy are you really getting?"

Bauer is particularly critical of conventional risk-sharing expectations, which, from the manufacturers' point of view, is often "risk-shifting" without an upside benefit. "Is it a partnership if you ask the supplier to cut the price, broaden the definition of test to include a lot of ancillary costs, carry the capital equipment cost and risk, cover any supplies management shortfalls, and, if he really wants the business, take on some legal liability?"

For their part, laboratories do show manufacturer loyalty, Bauer says, which might explain why fewer products are being considered in laboratories' purchase cycles. "If someone has a relationship with one specific manufacturer, that manufacturer does things over the term of the contract to build favor; they're giving considerable good will going forward. I think that's generally been the nature of partnerships: Treat me rightand I'll give you preferential treatment." And, he points out, the administrators aren'tcoming down to the laboratory people and pressing them to make an exhaustive comparison of multiple manufacturers. "If they were asking for a million dollars, the administration would say, 'What are the other options?'"

When asked about risk-sharing's potential negative effects, ACL's Vance concedes, "I think we're pushing the envelope."

"It's a new concept," she says, "and some of the vendors are having trouble understanding what's included in a cost-per-reportable. We're also asking them to give one cost-per-reportable for all of our locations, whether it's a 900-bed hospital or clinic seeing 50 patients per day, and because it's a new concept, the vendors often have to structure data differently in their own organization."

Both the vendors and ACL are still learning what types of data are needed to ensure the equipment is being used optimally, she adds, and the contracts take this into account. "We typically build in a range, so that if the volumes used for the negotiating process go X percent over or under, it's a trigger for either party to come back to the table and look at the pricing again."

Bauer cautions that if laboratory professionals remain relatively insensitive to the manufacturers' tight margins, it will come back to haunt them. "In the past, some manufacturers have been driven to 'cave' during price negotiations and, even though

they were bringing innovation to the laboratory, they felt obligated to make price concessions," he says. "The manufacturers were trying to compete too aggressively onconsolidation of services, broader offerings, and cost reduction, so they kind of fed on themselves and brought the margins down in the industry."

Unlike other technologies such as computers, for which manufacturing costs drop as technology evolves, Bauer says, "a lot of the innovation in diagnostics relative to improving laboratory operations is not being delivered on a more economical basis." These benefits are coming from increased and costly mechanization, not better science. These are mechanical products–steel, motors, syringes, 'rust-up' subassemblies that just cost a lot more money on a per-test basis," Bauer says.

How will laboratorians, accustomed to an almost unending stream of innovation, react to a less dynamic diagnostics industry? Isn't the need for innovation perpetual?

The industry's R&D investment level, as a whole, is declining, as is venture capital interest, according to Bauer. "It's a trend that warrants some consideration. The big blood-screening laboratories, for example, are incredibly strong buyers in the U.S., and very cost-sensitive, but they have a long history of being careful not to shop innovation out of the market. They have been careful to foster innovation and preserve competition in the way they award contracts and structure their partnerships."

Others express skepticism that innovation is at risk. In fact, Dr. Sodeman says, vendors may have innovated so much that laboratories are reluctant to lock into long-term contracts. "Vendors want contracts to go out five years or more, but we'll frequently write them in the three-year range because the technology is changing so fast. We want to maintain our options out there."

If there is a gap in technology advances, it is for the smaller hospital laboratory, Dr.Sodeman says. "A lot of manufacturers out there are driving toward instruments withvery high throughput and very fast speed, and that's not necessarily a demand in this rapid response market," he says.

"The small labs that combine chemistry and hematology generally do 55 or 60 tests, and you end up with multiple instruments sitting around," he continues. "Sometimes quality control and maintenance cost more than the tests you run through it. We need analyzers that combine both straight chemistry and immunochemistry with a small footprint and where throughput -isn't that critical, and people aren't designing equipment for that environment. I guess there hasn't been enough consolidation yet."

Bauer's research confirms that the diagnostics industry has not been focused on smaller hospitals. "If you went back in the '70s, manufacturers were targeting the 200- to 400-bed hospital because it was less demanding and more profitable. Now the target institutions are larger because of consolidation. The majority of work is being done there, or controlled from the larger laboratories. But will it be going another step up? I don't know that I see that in the near term, particularly with laboratories' timidness toward robotics and automation."

CaseBauer did a study in 1993 that predicted "the economies of scale beyond what's associated with a typical 600-bed hospital were not significant," outside of densely populated cities like New York or Atlanta, Bauer says. "After that, your size has exceededthe available instrumentation, and you have transportation issues to deal with."

Says Sutter's Stephens, "I honestly can't say I take vendors' research and development into consideration in the development of our contracts." He believes that R&D occurs in the marketplace regardless of a specific relationship, and that the market as a whole is going to determine where various platforms are heading. "I don't know that a partnership between an IDN and a specific diagnostic laboratory company will inherently culminate in anything significantly different than what might otherwise occur," Stephens says.

Vance feels that ACL has been responsive to many of the vendors' needs, especially in working with them on developmental projects or participating in feedback panels to help vendors understand what the marketplace needs and how to develop products that are more user-friendly.

However, she warns that laboratories may not like finding themselves on the receiving end of consolidation wherever the number of vendors dwindles. "As the companies continue to merge, it sometimes impacts their service levels and product development,and it's something we're always keeping an eye on."

"For example, in the blood bank reagent market, there's been consolidation after consolidation, and it's now down to two vendors," she notes. "The pricing for traditional blood bank reagents keeps being increased–literally multiple times on an annual basis, and neither of the vendors now can handle the entire market, so there's no negotiation leverage for any size organization." Vance is not concerned at this point, though, that the same will occur for the larger product lines. "I may be very Pollyanna-ish, but I don't think in most cases the market will allow that to happen."

"I worry about whether some vendors are going to be around," Dr. Schamberg says, noting that two computer vendors were acquired in the last year. Several of the major companies seem to be committed to the diagnostics industry, but not all of them, he suggests. "As things get bought and sold, it does change the marketplace. It changes people's commitment, and you have to factor that in when choosing a vendor. You want them to be there."

That commitment factor is one reason why damage to one of the parties to a laboratory contract can cut both ways. It's more than an issue of who holds the most cards, Dr. Schamberg says. "We need to work with vendors on standardizing a big platform like hematology, because the reality is the relationship, if it works, is probably a 10-year relationship going

forward. When we negotiate with a vendor we don't want either party to walk away feeling beaten up and having lost something."

Dr. Sodeman agrees. "I don't know what the vendors' margins are," he says. "What I do know is that as a purchaser I don't want to drive a company to a margin that is not comfortable for them. I don't want somebody to come in here and put something in undercost, because they'll be unhappy. And there's nothing worse than having a piece of equipment and an unhappy vendor."

Anne Paxton is a writer in Seattle.

CaseBauer
Business Development and Research

An Executive Interview with Robert J. Bauer, President of CaseBauer

Diagnostic Insight, Winter 2002, Vol.29, No.1, pp.2

Robert Bauer grew up in shadow of DuPont's corporate headquarters where his father, a chemical engineer, made his career commercializing new technologies. Bauer earned his degree in biology from Villanova University in and his MBA from the Wharton School of Business at the University of Pennsylvania. He cut his teeth in IVD with two start-ups in the late 70's and moved on to R&D and marketing positions with Becton Dickinson International and Abbott Laboratories in the 80's, followed by a stint at Boston BioMedical Consultants in the early 90's. "A lot can be said for being in the right place at the right time. I lived through the boom days of IVD and had more than my share of choice assignments. I was fortunate to have an opportunity to work for and with some very talented individuals."

Bauer was President of the Biomedical Marketing Association in 1990, served as a board member and advisor until the end of 1997, and is a recipient of the BMA distinguished service award. Mr. Bauer is also a founder and principal in SunWest Homes, a real estate development company based in Dallas. In his spare time, he relaxes on his sailboat, skis the Rockies, and is an avid runner and cyclist.

When CaseBauer was founded in 1991, Bauer says he was determined to create consulting tools to fill a gap he experienced during his corporate days. The firm specializes in diagnostics, laboratories, imaging, and point of care and operates in 14 countries. Services include multinational political and macroeconomic analysis, business-foundation packages, strategic benchmarking studies, market research, proprietary market modeling, business and technology valuations, investment due diligence, and new product fatal-flaw analysis. CaseBauer pioneered market simulation models for the IVD industry, based on multivariate statistical methods. A typical analysis using 8,000 to 50,000 simulations can predict potential market share capture, price sensitivity, and the net present value of product features.

After 10 years of successful multinational engagements with a cross section of the largest and smallest IVD companies, he has developed a unique perspective on an industry that has undergone a substantial transformation during his professional career. In the following interview, Bauer talks about the industry and where its headed.

DIAGNOSTIC INSIGHT: What would you say is the general state of the IVD industry as we come to the end of 2001?

BAUER: Clearly the market is showing recovery from the difficulties of the mid to late 90's. After hitting a valley in 1998, we now have growing revenue and profitability. In fact, worldwide IVD growth almost matched that of the Pharmaceutical industry last year. The industry which had been turning in single digit pretax margins, is now seeing an average of 10% to 11% for the major players.

We expect this trend to continue, but don't expect to see double digit sales growth in the near term. An overall market growth rate of 6-8% from now through 2005 seems more reasonable.
Its also good to see that we are finally reaching some level of price stabilization. The consolidation of providers and the increased influence of group purchasing organizations, coupled with competitive price slashing in the late 1990s resulted in some pretty significant price erosion in an already shopped down market. Providers, physician groups and the manufacturers have all had a taste of it now and price discounting has tempered somewhat. The IVD industry has adjusted to the new environment and has become more adept at understanding the value of profitability vs share.

DIAGNOSTIC INSIGHT: To what do you attribute this recovery?

What we saw was a correction. But, for the most part, the fundamental drivers of market growth have remained intact.
I don't believe anyone would dispute that their had been poor management of test ordering and, in some cases, even abuse. With little pressure, testing volumes corrected, possibly even over-corrected in some areas. I think this correction has run its course.
Recovery is being driven by growth in the number of healthcare procedures, both as a function of an aging population base in the G7 countries and improved access to healthcare services in developing nations. While there has been some

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rationalization of services, mostly through systematic reductions in the number of hospital beds and a reduction in the average length of stay, the affect on diagnostics has been relatively minor.

It also helps that the use of new, higher value products and technologies is increasing in areas such as critical care, viral disease management, and diabetes management and at the same time newer, more labor efficient automated workcells are coming on line in many laboratories.

We are also seeing growth related to better utilization of some of the existing tests. This is the flipside benefit of the trend to achieve greater standardization of medical practice and procedures. A good example is in diabetes care where a significant portion of the diabetic population is not being tested at the recommended frequency. There has been a continued increased in the utilization of diabetes tests because of new ADA testing guidelines and benchmarking efforts, such as those being conducted by HEDIS in the United States.

We can't lose sight of the fact, though, that there has been a philosophical shift here in the US, as well as in Europe and Japan, from growth driven by "pride of technology", to a more fiscally responsible approach to "technical medicine" such as pharmaceuticals and laboratory testing. It wasn't that long ago that European governments and healthcare providers took great pride in their healthcare technology and reach. This has changed. Now the focus is on harmonizing and strengthening the economy of Europe and healthcare costs play a major role in this. This factor will temper the recovery somewhat, so I expect European growth to lag that in the US and I don't expect to see a near-term return to the worldwide growth rates of the 80's.

DIAGNOSTIC INSIGHT: You mentioned growth generated by new technologies and products. Which types of technologies and products do you see as being the most successful in this new IVD environment?
BAUER: To be successful, new products must materially affect the clinical decision process or, as in the pharmaceutical industry, catch on in the public eye. Troponin is an a good example of a product that has had a substantial effect on clinical decision making. Cholesterol and PSA are good examples of products that have caught the public eye. Her-2-neu breast cancer tests are a good example of both. Breast cancer is a very high profile disease with strong patient advocacy groups that have influenced the adoption of this new technology.
The one thing we have noticed, however, is that the standard for "affecting the clinical decision process" is not just technical, it is also practical. Even if the test result supports theoretically better medicine, it must be provided in an environment where other factors such as liability and public opinion do not limit its utility. This is not always an easy concept to get across to an inventor. If a test, for example, identifies patients who are not appropriate candidates to receive a specific treatment, but there is a potential political or legal liability in denying that procedure to them, then the test may not be all widely adopted.
To answer your question more specifically, some of the most interesting growth areas today are in critical care, molecular diagnostics, diabetes care, and cellular diagnostics.
Looking farther out, the whole area of genomics is exciting, especially in the area of drug therapy and cancer. However, as we have seen with the development of nucleic acid diagnostics, this won't happen overnight.

DIAGNOSTIC INSIGHT: And do you think that reimbursement will follow as the clinical need is established? What about the failures?

BAUER: IVD has faced a comparatively tame reimbursement and regulatory environment for most of the products currently on the market. For truly new clinical tests, reimbursement has always been a battleground. Regulatory approval has also been a challenge. A lot of companies dealt with this whole area by simply avoiding certain parts of the market.

The real question is how many products have the earning potential to substantiate the investment and delays imparted by the regulatory process?

The problem really varies depending on the test application.

Tests for the outpatient market face the greatest challenge because reimbursement is on a per test basis in many markets and the value is formally determined and set at the beginning of the product life cycle. These products also need full regulatory approval to be on the market. This poses a dilemma for some potentially high value tests. For example, we recently evaluated a new serology test that will likely be launched on the basis of substantial equivalency to other serology markers, and reimbursed as such. The true value of this test, however, could be as a unique predictive marker that will substantially reduce the morbidity and mortality associated with a highly complex medical procedure. It will take several years of clinical experience and data to support this claim, however, and even if it is established and regulatory approval for this claim is eventually granted, reimbursement will already be set at the lower level. It would seem best to fund the required clinical studies to substantiate the higher value claim before entering the market, but not many start-up firms can afford this luxury, and in the case of this marker, while it is a substantial opportunity, it is not one that would likely attract investment at this level from one of the top five IVD companies.

Inpatient tests are easier than outpatient tests. Most are covered by more global budgets where there is little formality and value is established at the physician or laboratory level.

Highly specialized tests, run in high prestige institutions, face the lowest level of difficulty. Research use only labeling is not a particular limitation in this setting.

Unfortunately, a lot of the biggest opportunities are for outpatient conditions. And without a doubt, the environment is not

very conducive right now in the US, and with the CE mark coming on line in Europe in 2003, it could get worse before it gets better.

A big part of the equation is the price of the manufacturer can extract in the market. Here, I think we also sell our technology short. IVD has had a "process" orientation that has heightened in recent years. The "clinical sell" is only present in a few areas today. The recent cardiac marker experience is a good example. One manufacturer entered with a well priced marker, but the price eroded as the test was leveraged to place instruments. The orthopedic device industry has $150.00 screws. We have $10.00 nucleic acid diagnostic tests.

Overall though, I think the regulators and the manufacturers will learn from the failures and in the long run the situation will improve.

DIAGNOSTIC INSIGHT: If you contrast company consolidation with the consolidation that has happened in the reference lab industry, where there was a consolidation that eliminated overcapacity, would you predict this will happen in diagnostics as well?

BAUER: We have to look at it in near term and long term. In the near term I think the kind of consolidation we are going to see will be mostly fill-in acquisitions, like the recent acquisition of Vysis by Abbott, where you are adding a potentially high value technical capability.

Overall, I think the drive to consolidation is cooling. There are a few reasons for this. All of the major players have made a significant acquisitions and in many cases are still assimilating their acquisitions; good and bad. And with a market recovery in progress, even at its current level, most companies are not feeling as desperate right now. Of course this is not universal.

Also in the near term there are some regulatory issues to be concerned about. Look at what happened with the Roche's COBAS Mira product line in the Boehringer Mannheim acquisition and with Syva's drugs of abuse line when Roche acquired Syntex . US and European regulatory agencies forced the divestiture of these businesses as a condition of the acquisition. On a larger scale, look at what happened to the recently proposed General Electric / Honeywell merger. Future mega mergers may not be approved, at least in Europe.

Further consolidation will likely be a function of how well the growth of cruenta technologies dovetails into the emergence of next generation products such as genomics. If there is a prolonged disconnect, I think we will see more consolidation at the top. It could, however, be very different consolidation than we have seen in the past. A lot depends on how the market evolves in some of the IVD growth sectors, such as molecular diagnostics, diabetes monitoring, advanced cellular diagnostics and hospital point of care. If these segments continue to grow they will account for as much as half of the market in the foreseeable future. Growth in these segments could force further consolidation in some of the mature, lower margin businesses such as routine chemistry and hematology. It is not necessarily companies themselves that will consolidate. We may see product line consolidation with a resulting reduction in industry overcapacity.

DIAGNOSTIC INSIGHT: It is generally thought that small companies need the infrastructure of larger companies to successfully market their products. Is this necessarily so?

BAUER: For me, this brings up the issue of cooperation of IVD companies, in general, regardless of size. Our industry has yet to optimize cooperative relationships between companies. When a small company is targeting a decentralized market, it may need the infrastructure of a larger company for distribution power. You can even make the argument that even if they are targeting a centralized market, particularly if it is a more mature market, they may need the larger company. For instance, they may not be able to build the instrumentation or guarantee the delivery required by a blood bank.

We have yet to see the kind of partnerships seen in Pharma where co-marketing among the major players is now common practice. As we move down the road and companies seek to grow their businesses, the current barriers to cooperation will likely erode and we will begin to see more cooperative relationships. Now, several large companies compete head to head in all product lines and do not want to cooperate even on secondary product lines. As newer technologies start to evolve, we will start to see companies experience varying levels of success in different areas and I think that it is likely the top companies will look less like mirror images of each other. As this happens, their willingness to cooperate will increase.

DIAGNOSTIC INSIGHT: Are you seeing more active discussions between pharma and diagnostic companies?

BAUER: Actually no. I think this is because most diagnostic companies are a near term oriented and pharmaceutical companies are very far term oriented in their product development. For diagnostic companies there is little motivation to partner with pharma because there is a fair amount of risk and time required to develop a pharmaceutical product. These partnerships may be more interesting to a smaller company because a smaller company because the relationship itself can help raise funds. This approach doesn't necessarily meet the net present value requirements of a larger company.

DIAGNOSTIC INSIGHT: Over the years as you have been consulting with industry, what are some of the surprises you have encountered?

This is a fun question. Let me take a stab at three things I've noticed.

The first one I'd call "the blessing and curse of corporate think". In my first assignments after leaving Abbott, I was surprised at how unique the cultures of the other leading companies are. And how much culture drives the way the market is defined, the way competitive moves are anticipated, how customers are seen, and how the future is projected. What was most

interesting is how each company's commitment to its culture has contributed to many of it successes. It is also these company's inability to think outside of their culture that contributed to many failures.

The second is the real value of multi-market analysis. At CaseBauer, 85% of our assignments are multinational. I noticed early on how much more could be learned about a specific business opportunity when multiple countries are analyzed in tandem. There is incredible insight to be gained in understanding how different markets contend with basically the same medical scenarios and products.

The final has been the historic instability of the IVD market leaders. This has probably been the most surprising thing. Over the years, the number one player, first Technicon, then Dupont, and finally Abbott did not leverage its leadership position and pull away from the pack. It will be interesting to see how Roche will fare.

CaseBauer
Business Development and Research

Laboratories Scramble to Find Replacement Supplies following FDA Ban on 125 Abbott Products

Clinica, December 6, 1999 Issue 887

On November 2, 1999 the US FDA agreed to a consent decree in which Abbott would discontinue manufacturing, distribution, and sales in the US of some 65 different blood and urine tests in a variety of platforms. The reaction from clinical laboratories has been significant.

Robert Bauer, President of CaseBauer, recently reported that while the products being withdrawn from the market impact less than 6-7% of the typical immunoassay testing volume, 50% of the laboratories surveyed by CaseBauer last week believe that the decree will "significantly" affect their laboratory's service level and budget this year. CaseBauer, a Dallas-based medical products consulting firm, surveyed 75 laboratory directors during the second week of November to gauge the outcome of this action.

According to Bauer, "the service level impact will largely be on test turnaround time (TAT), especially in the short-term." Forty-one percent (41%) of respondents anticipate an increase in laboratory TAT as a result of either sending tests to another laboratory or moving STAT assays to slower "backup" analyzers already in the laboratory. Several of the withdrawn products, such as primidone, lidocaine, CRP and hCG, are provided on a STAT basis in many laboratories.

Additionally, 40% of the directors said that changing products will have an impact on the clinical values and critical ranges reported to physicians and will require re-education of their physician base in some cases. Thirty percent (30%) anticipate the need for re-programming of their laboratory information systems.

From a cost perspective, laboratory directors told CaseBauer that, on average, they initially expect to spend more than $17,500 to work through this situation. The biggest anticipated expense is re-training; particularly the re-training of nursing staff that have been using CLIA-waived TestPack kits, the training of laboratory staff in the use of new analyzers, and the training of physicians on new clinical values and ranges. Re-training accounts for a third of total estimated costs of conversion."

CaseBauer's initial projection of the cost to US laboratories and physicians offices exceeds $85 million. This is in addition to Abbott's $100M fine and anticipated $68M in costs.

Inventories Rapidly Depleted

"This was over before it started" stated one laboratory director, "everyone's inventories were almost immediately depleted, and now we are forced to send out STAT tests like CRP, to an outside commercial laboratory."

According to Bauer, "IMx and AxSym assays, for the most part, are being shifted to alternate analyzers that are either already in place or being acquired, TDx assays are generally being shipped to other laboratories or shifted to back-up systems already in place, and TestPack is being replaced by alternative products (e.g. hCG), either from Abbott or alternate suppliers."

Abbott is clearly taking action to minimize the damage. Some laboratory directors have reported that Abbott has offered to offset some or all of their incremental costs in future rebates, and has offered manpower support for comparative studies. Abbott does have some substitute products and is providing inventory to some sites.

FDA Changes its Stance

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On November 23, 1999, Abbott announced that the FDA agreed to amend the Consent Decree to delay the product ban for an additional 30 days, from December 6, 1999 until January 10, 2000, in response to requests from laboratories and the Clinical Laboratory Management Association for a longer transition period.

This action addressed a key criticism of the FDA. According to Bauer, "One-third (33%) of the laboratorians surveyed attribute the FDA action to a "bureaucratic impasse" or just an indication that "FDA is asserting its authority." Many of these laboratory directors felt that the FDA penalized them more than Abbott.

Laboratories Reconsider Future Purchasing Practices

"Many laboratories confided to us," states Bauer, "that, after being challenged to find, qualify, and put alternative tests on-line in less than 30 days, they will change their purchasing practices to hedge against this kind of vulnerability in the future." One Mid-west director told CaseBauer "we learned a valuable lesson... we will not put all our eggs in one basket in the future."

At this juncture, more than half (59%) of the laboratories surveyed stated that they were undecided about long term product commitments and were open to alternate suppliers for the banned products long term.

The FDA extension is significant in that it allows a greater opportunity for laboratories to stockpile supplies rather than rush to qualify alternates products over the shortened holiday month of November.

CaseBauer is a business development and research consulting firm specializing in diagnostics products and operating in 14 countries in North America and Europe. CaseBauer is headquartered in Dallas, Texas (inquiry@casebauer.com).

CaseBauer
Business Development and Research

Perspective on the Point of Care Testing Industry

Diagnostic Testing and Technology Report, 1999 Interview

Excerpts from an interview with Robert Bauer, President of CaseBauer (Irving, Texas), conducted on October 1, 1999 by Jon David Klipp, Editor of the Diagnostic Testing and Technology Report.

Klipp: How big is the POCT market and how fast is it growing?

Bauer: Point-of-care testing is 15% of the total IVD products market, about $3.3 billion, including hospitals, physician offices and patient self-testing products. We're projecting annual revenue growth to be in the 13% to 15% range. (Note: Worldwide number)

Klipp: What is driving the growth of point-of-care testing?

Bauer: In recent years, growth has been driven by an increase in the acceptance of point-of-care products that were introduced in the 1980's. A number of factors contribute to this - most notably outcomes studies, the institutionalization of procedures by managed care, and physician awareness. For example, when the Diabetes Control and Complications Trial (DCCT) was published in 1993, it sparked significant growth of glucose self-testing products - products that had been on the market for almost a decade. Motivated healthcare system began to provide infrastructure, such as patient training and monitoring, and education of physicians. Payers jumped on the bandwagon and provided incentives, such as HEDIS quality certification, which sets targets for increased testing.

Point-of-care testing opportunities can have long lag times, particularly those directly involving patients. It's an incredible task to educate and motivate 10 million diabetes patients, 100 thousand physicians, as well as the providers and insurers.

Klipp: In particular, what has been the point-of-care testing trend in hospitals?

Bauer: Interestingly, the drive toward centralized laboratory operations has catalyzed the value of point-of-care testing in hospitals. Physicians in the emergency room used to be able to send samples two doors down to the hospital's laboratory. Now, with testing centralized in a core laboratory on the other side of town, point-of-care testing becomes a more viable option for a lot of time-sensitive tests. We have encountered laboratory directors in highly centralized laboratory systems supporting manual testing alternatives. Putting manual tests at the point-of-care allows them to retire instruments that have been maintained just to meet STAT testing needs.

Klipp: What are the biggest barriers to the growth in point-of-care testing?

Bauer: For patient self-testing, there are three common barriers. The first is technology, providing accurate tests that are reliable in the hands of unskilled users. Technology is improving but still requires, in many cases, periodic calibration and quality control procedures that are beyond the capability and interest of non-laboratory personnel.

The second is clinical utility. There must be a compelling motivation to test in the mind of the tester, whether this is a patient, a doctor, or a nurse, and there must be actions to take based on the test result. In the case of a pregnancy test, this is clear. You quickly decide to tell your husband, call planned parenthood, see your OB-Gyn, whatever. Action needs to be taken. With cholesterol, the motivation to test is lower, and the required action is pretty much see the doctor at your earliest convenience.

The third is costs. Laboratory directors and administrators hate to spend $10 for a point-of-care test they can run in the laboratory for $0.88. Payers have raised barriers to physician testing over the past decade, with some going as far as to specify laboratories for testing.

In the United states you can add a fourth barrier - CLIA operating protocols enforced by the CDC. Short-term, this won't get

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any better as the enforcement of CLIA is being transferred to the FDA.

KLIPP: Which segments of the point-of-care testing market are growing the fastest?

BAUER: On an overall unit basis, diabetes. Glucose testing and related ancillary tests, comprise about 50% of the overall market for point-of-care testing.

On a percentage basis it is much harder to say. Rapid tests aimed at patients in the emergency department, such as chest pain diagnostics, are growing quickly.

Klipp: How do you determine the costs and benefits of point-of-care testing?

Bauer: It's not the direct savings of the testing such as specimen transport savings that provide the benefits, it is the larger and more difficult to quantify downstream costs. For example, if you're reducing the complications of deep vein thrombosis therapy by stabilizing patient clotting times more rapidly with a point-of-care test, the payback is significant and hospitals have the wherewithall to make the investment and reap the benefit. Hospital administrators are motivated to reduce ICU days that can cost as much as $3,000 per day. In the scheme of things, it really doesn't matter that it can be done $1 cheaper in a core lab.

At the same time, public health agencies would love a point-of-care test for chlamydia, but their ability to pay is much less, and the benefit is not directly realized by the public health entity that does the testing.

CASEBAUER
Business Development and Research

An Executive Interview with Robert Kisabeth, M.D., Medical Director of Mayo Medical Laboratories of the Mayo Clinic

Diagnostic Insight, 1997 Interview

Robert Kisabeth, M.D., took an interesting route from Newport, Tennessee where he grew up to the position he now holds as Medical Director of the Mayo Medical Laboratories at the Mayo Clinic in Rochester, Minnesota. While his interest in mathematics could have led him in a vastly different direction, he is extremely satisfied with the path he chose. "I was a physics major at Union College in Schenectady, New York, and at the end of my sophomore year I decided that although mathematics was fascinating, it was not as fascinating as people were," he explained. "I was trying to imagine how I was going to earn a living as a physicist, so I decided to carry my interest in science into medicine." He attended medical school at the University of Tennessee in Memphis from 1968-1971. Working his way through medical school as a blood collector and later as a bench tech at a laboratory in Methodist Hospitals of Memphis gave him a view of what the laboratory could mean to the care of people with many different types of diseases. "The question was whether to become a general internist, a general practitioner, or a pathologist, and since I had a privileged view of lab medicine, I decided to go into pathology and laboratory medicine," Kisabeth said. After completing his residency, he worked in a large general pathology practice – the Duckworth Pathology Group – until 1989. At that time, despite some trepidation about moving to "the tundra", Kisabeth and his wife moved to Minnesota where he began a position at the Mayo Clinic as a pathologist. Two years later, he was named Medical Director of Mayo Medical Laboratories. "We've been absolutely delighted from the day we arrived – we couldn't ask for a finer life," Kisabeth said of his move north. "It's a wonderful group of people with whom to practice medicine – it has been a totally positive experience. " Kisabeth and his wife have two daughters, aged 14 and 16. In addition to his duties at the laboratory, Kisabeth also serves as Chairman of the Mayo Clinic's European Task Force, which evaluates opportunities for Mayo to constructively serve the interests of European communities in aiding sick people. While his work involves "an extraordinary amount of travel, "which limits his free time, Kisabeth enjoys building furniture and cabinetry when he has a few spare moments. Regarding his hectic work and travel schedule, he said, "My vocation has turned out to be my avocation. But I have no complaints; I don't work for a living -- I just practice laboratory medicine." In the following interview, Kisabeth shares his insight about changes in the delivery of health care, current laboratory practices, reimbursement concerns, and other issues involving diagnostic testing.

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Bauer: In your 20 years as a physician and most recently as medical director of the Mayo Medical Laboratories, what do you feel have been the most important changes in the delivery of health care?

Kisabeth: Most physicians my age have been part of a health care system that has been inexorably and continuously commoditized over the years. The commoditization can actually be traced back about 25 years when insurers, HCFA, and the American Medical Association set out to design an "improved" means for medical billing. As you know, they developed the RBRVS (CPT codes), which codifies all tangible procedures of health care. The problem with this approach is that it is based on relative cost, not on relative value. Why? Because procedural costs are easier to define and tangible costs are easy to characterize. The problem is, however, that this system places little value on the important and valuable intangible aspects of medicine, such as researching patient histories, physical patient examinations, and knowledge of the patient and the patient's environment, etc. The best-reimbursed things in health care are procedures. As a result, the entire health care system shifted its focus to tangible procedures. Medical specialists' revenue in the last 20 years has been associated with procedures. Medical students have gravitated toward procedure-intensive specialties. The laboratory industry has also focused for the last 20 years on revenue-associated procedures–not on the contribution of laboratory tests to the improved management of patients' illnesses.

Bauer: Do you see managed care and captitated reimbursement as improving or exacerbating this situation?

Kisabeth: Theoretically, there are good things associated with capitation. . .that expertise in health care would focus on preventing illnesses and thus costs, thereby reducing waste but we have not seen what we might have imagined would occur. There is a conflict of interest in the system today. When you add profit initiatives to capitation, you end up with a

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provider of services looking at short-term objectives– quarterly or annually. Chronic heart problems and chronic inflammatory diseases, like rheumatoid arthritis, really have to be looked at in the longer term to appropriately define the financial context in which to apply controls. But as providers bid on capitated contracts, their intent as it relates to the treatment of hypertension might be, for example, to minimize the number of visits and the overall cost of caring for the patient over a one to two year period.

Bauer: It is a common perception that this conflict of interest can be mediated by establishing a metric to compare the outcomes of different providers. What is your perspective on this?

Kisabeth: It is true that some have suggested that this conflict of interest can be countered by the creation of outcomes measurement that would in some way be published, making clear to the purchaser, patient, and employees which plan works best. The problem is that one cannot get a realistic view of one organization vs. another in treating the patient unless one looks at the treatment of patients over a 20-year period. For example, in hypertension, does the provider that enforces compliance of therapeutics lessen the incidence of heart failure over one that does not enforce compliance? You can point out all the normal blood pressures you want, but to truly determine if one provider is outperforming an other will require a study period long enough to measure the impact on heart failure. I picked this example because it is very real; the 3.5% of patients with high blood pressure consume about 40% of the hypertension-related expenditures. Population-based reimbursement is simply another way to focus on costs, but it has a very serious and unintended consequence: providers have an incentive to keep sick people out of the system.

Bauer: If the current approach is flawed, what do you suggest?

Kisabeth: In this country, unfortunately, we use specific diagnoses, meaning ICD9 codes, to categorize our patients. And, let's face it, in many cases, we use diagnostic tests not to evaluate myocardial infarction but to confirm a presentation of it for reimbursement purposes. This is clearly the wrong orientation. It would be more effective if payers paid per illness or per episode of care. An illness basis would work best for long-term care such as diabetes while episodes of care would be best for acute illness such as chestpain. This approach would allow the organizations that provide care to better focus on applying resources to the patient. Some countries use Reed codes, which are not diagnoses, but define a patient's problem by complaint. Patients would rather pay based on how they present to the doctor–not on their diagnosis. Being paid for the diagnosis makes no sense at all. We're not caring for a diagnosis; we're caring for a patient who presented with a specific set of problems. An example of this problem is with laboratory tests that are paid only when certain diagnoses are present. At Mayo, we see many patients who do not have a diagnosis, yet they often require an extraordinary amount of time and expertise. In a CPT-based system, time and expertise have little value. The incentives are all for a quick, even premature, diagnosis.

Bauer: Our observation is that many laboratorians really aren't active in the clinical process. They are more focused on the operations of the laboratory as a plant. Why is this?

Kisabeth: I think this is a consequence of the commoditization of health care. As administrators look for ways to save money in health care, laboratorians have responded by reducing the cost in the lab or reducing the number of labs–again, thinking that the task was to minimize the cost of the procedure. The real issue is how can the laboratory be used more effectively in reducing the overall cost of care? The point here is not to look at the laboratory as an isolated venue for improvement, but to look at the medical process or, more specifically, the disorganization of the process. The big gains are in overcoming entropy and organizing the process. Unfortunately, many of the incentives established by insurers actually inhibit this approach. The improvements will come from integrating the care process, not propagating artificial boundaries. We've prided ourselves on minimizing the cost of analysis rather than on optimizing the cost of analysis. Minimizing has become the watch word of laboratorians. At Mayo, we prefer the term optimizing–first establishing very carefully the clinical and analytical objectives, and then minimizing cost within that context. That context might also include, for in stance, frequency of delivery. What we have done for so many years is maximize batch size. It's ludicrous really. In an overly simplistic search for economies of scale, many laboratorians have minimized the cost of the procedure without considering the context. Batches are now beginning to dissolve at Mayo and almost all tests are done on an ASAP basis.

Bauer: With the commonly espoused "hub and spoke"concept, many believe that laboratory tests that are not STAT should be done in remote centers for greater economies of scale. How does this fit with your philosophy of optimizing test cost?

Kisabeth: That to me is an arcane notion. If one looks at the case mix at any hospital in this country, one finds that today's inpatients have increased substantially in severity and complexity, and the kind of laboratory support needed is extraordinary compared to what it was 20 years ago. Our task for patients in the hospital is not only to maintain them until we can move them to an unoccupied bed but to diagnose them and treat them as quickly as possible. I think that the notion of having only STAT tests within the hospital is an ill-conceived notion that reflects a lack of understanding and familiarity with real group medical practice–and this decreasing familiarity is largely a product of having practiced in a boutique environment.

Bauer: Considering where insurance is today–managed care, integrated health care delivery systems–what are the implications for the future?

Kisabeth: I think patients and purchasers will ultimately decide whether our notions make any abiding sense. When we survey patients, their desire more than anything else is that we, in the health care system, communicate better. One of the most consistent complaints patients have is that, as they move from one specialist to another and from one care setting to another, there is virtually no communication. In response to this patient mandate, we will see the integration of the provision of medical services. And the best place for integration to occur, because it requires the ongoing communication and working together of health care professionals of all kinds, is within the community. Care plans, decisions regarding formularies, and the diagnostic test and therapeutic modalities that work and do not work for patients will be decided on a community basis. This is in the best interest of quality care, and the best interest of cost management. Another reason the community is important is that it's difficult to deliver care without first caring. This may seem corny on the surface, but it is very true. And it's probable that such caring can occur only at a community level. So if we can move technology as near as possible to a person's hometown, not only will the care be less expensive, but it could be perceived by patients as far more acceptable because it will be delivered in a traditional and caring manner, by people who actually know the patient– strange as that may seem in today's environment. Along with this, we will see a reappraisal of medical technology with regard to whether it really benefits patient care. I think no segment of medicine will face more of a reassessment than the laboratory/diagnostics industry. One of the greatest opportunities for laboratory medicine to pursue in the future is a larger role in the treatment of sickness. Wouldn't it be a tremendous cost and quality benefit if we could tell patients more consistently, through good laboratory testing, whether their treatment had been effective, and whether that treatment–which is probably very expensive–could indeed be stopped?

I think another opportunity for the diagnostics industry will lie in ascertaining whether a metabolic pathway requires any therapeutic intervention.

Bauer: Many insurers do not reimburse a new and experimental technology without years of established use or extensive data, and diagnostic products generally do not generate the financial returns to substantiate such a clinical analysis. What does this mean for the future of laboratory technology?

Kisabeth: Diagnostic products don't earn that return because they've been sold as sources of incremental revenue instead of sources of a reduction in overall cost. I think absolutely that payers will pay for it, but we're going to have to show them that it's more valuable to do our tests and reduce downstream costs and enhance quality of care. The only way we're going to do that is to demonstrate validity, and if it takes years to do that, that's what we're going to have to do. But in most cases it doesn't take years– it just takes effort.

Bauer: What are some diagnostic tests that you consider very valuable?

Kisabeth: Most of our laboratory tests are very valuable, when properly used. I'm not one to decrease testing–I don't think that's the key to reducing overall health care costs–but I do think there are tests that we should not be doing, that we could better spend that money on other tests, procedures, drugs, or health care services. Today, many tests that we perform will not improve patient care if not adequately controlled. These tests, in fact, can have serious potential for causing harm. For example, within the laboratory community we have normative behavior standards of quality control. These standards, however, are based on the operations of the test procedures, and not on their downstream clinical impact. Let's take PSA, for example. If the mean for this assay on a given day, on a Levy Jennings plot, were to move 0.7 standard deviation, many would say this falls within acceptable standards. We often don't consider that such a deviation–in their community, for example–would result in more than nine men being selected for biopsy and ultra sound rather than 2.5 who should have been selected. So we must seriously question the basis on which we set our standards. Are our standards in the context of our operations, or in the context of the patient's care and the overall cost of that care?

Interview conducted by Robert Bauer, president of CaseBauer & Associates, a business development and research firm operating in 14 countries.

CASEBAUER
Business Development and Research

Contemporary Service Strategies Changing with Changing Times

Diagnostic Insight, Summer 1996, Vol. 23, No. 3, p. 10-11

As we hurtle toward the end of this decade, rapid changes in healthcare delivery are creating new opportunities for service products. Healthcare provider mergers are spawning new organizations that are larger and more businesslike. With size and purpose comes buying power —and a re-evaluation of service needs. Barnes Hospital and Jewish Hospital of St. Louis, which merged to form Barnes and Jewish Hospital in 1992, merged with the nine-site Christian Health Services in 1994 to form the Barnes Jewish Christian Health System. While Barnes had a well established, internal clinical engineering department, Jewish Hospital contracted its work to outside vendors. A team appointed to integrate these approaches, in the end, established an in-house command center that coordinates all internal and external service providers. Now, with the total system expanded to 16 acute-care and seven long term-care facilities in Missouri and southern Illinois, the internal biomedical engineering department has gone from a budget of $650,000 to $7.5 million and from 14 to 60 employees. Big buyers, like Barnes, have big leverage. As the service manager of one leading supplier noted, "It is typical for a [consolidated] customer to ask for a contract that costs 95% of last year's and at the same time demand that average response time be reduced from eight to four hours. " But there is more to size than the ability to exert price pressure. The consolidated buyer is emerging as a very different type of customer, one with different needs and with a different perspective on the process.

The Service Net is Broadening

While there is much talk of standardization of laboratory equipment, service may actually lead the way. Historically, service has been a very localized event. Product service was valued as a function of the local service organization or technician. If the laboratory had a competent service representative and the manufacturer had a good track record locally, service was good. Today's regional or national buyer has a very different view. In these larger consolidated systems, where decisions are more and more often being made centrally, simpler and more comprehensive service solutions are preferred, both across facilities and departments. "I'm looking to link six instruments together with a robotic system, and I certainly don't need six suppliers telling me that a failure is in the other manufacturer's equipment," says an administrator from a large East Coast medical system. Service standardization stands to create a whole new market dynamic: "critical mass". This will attract third party service organizations that heretofore could not justify participating in the highly fragmented IVD market. One chemistry manufacturer is even piloting a broad base, multi-brand service product through a joint venture with an independent service provider. The company's vision is to provide total chemistry laboratory service on all brands, not just its own. It is also not unusual to see other manufacturers banding together to offer consolidated service programs for specific applications.

Service Needs to Fit Better

Big buyers want service that fits their workflow and organization, not the manufacturers'. For example, instruments are being designed for simpler operation and it is well known that laboratories have hired less qualified staff. This has created a need for service organizations to participate in initial correlation studies and on-the-job training—a move that big buyers welcome. Some manufacturers are responding by re-evaluating the skill set required for field service. Traditionally, there have been field service engineers —the electromechanical service technicians, and technical service representatives —the medical technology support team. In recent years, a hybrid called diagnostic system specialists has emerged: medical technologists with electromechanical service responsibilities. Today's buyer is also considering the backside cost of maintenance intervention; that is, the cost of laboratory disruption caused by service calls. Considering how often a service representative "invades" the laboratory, and the magnitude of service calls across the healthcare system, this service invasion is huge. Because of this, buyers are placing a higher premium on off-peak service calls. "Saturdays are now almost as busy as weekdays," relates one major hematology manufacturer.

Uptime is More Important Than Speed

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Buyers' real objective is to improve uptime, and they are generally moving toward a common measure of uptime performance. Some buyers are now demanding that service contracts be more specific, both in terms of system uptime guarantees and failure recovery times. This is a shift from intermediate measures used in the past, such as telephone and on-site response times. Large reference laboratories are leading this initiative, but hospital laboratories, as they come under increasing productivity pressures, are making recovery times a high priority, too.

The Mix is Changing

Four years ago, 80% of new immunochemistry system customers bought the standard annual contract. But as laboratories try to reduce cost, they are abandoning the convention of annual service contracts and embracing a wide variety of service arrangements. "Now, only 20% buy an annual contract while 80% opt for a customized contract, insurance, or some other arrangement, such as time and materials," reports one manufacturer. CaseBauer & Associates has found that the purchase of insurance policies to cover automated chemistry analyzer service costs has grown from 3% of all system placements in 1991 to an estimated 10% in 1996. In another effort to avoid annual service contracts, buyers are effectively extending warranty periods by negotiating three- to five-year service commitments into instrument sales agreements. One hematology manufacturer is seeing 40% to 50% of its high-end new system placements made with a five year service agreement.

The Challenge is Clear

When one considers the changing needs of the marketplace and the increasing product parity among major manufacturers, the equity of service in the overall product value proposition stands to rise. These trends are creating an opportunity to develop service differentiation. The challenge is for service organizations to make products that become a bigger component in the management of their customer franchise.

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An Executive Interview with Beckman's Chief Operating Officer, John P. Wareham

Diagnostic Insight, 1995 Interview

John P. (Jack) Wareham was born the second of three boys in a small town in Iowa, where his mother still lives and where his father was a pharmacist. Wareham credits his father as being a major influence in his life. "He was what I call a 'real professional pharmacist', who really thought he made a difference and knew how to help his customers. So I grew up with a great sense of the customer, and of course when you're in the retail business, it's hard work, long hours. I think he had a lot of influence on how I ended up running my career, because I always think instinctively about the customer." Following in his father's footsteps, Wareham earned his degree in pharmaceutical chemistry at Creighton University in 1964. While working as a pharmacist from 1964 to 1968, he earned an MBA in finance from Washington University. After receiving his MBA, he went to work for SmithKline Corporation, rising from Corporate Management Trainee in 1968 to Vice President of Beckman's Diagnostics Systems Group in 1984. When Beckman Instruments became a separate company in 1988, he became Beckman Group's Vice President, then became President and Chief Operating Officer in 1993. He lists his interests as golf, classical and Broadway music, and art, especially the styles of Monet and Renoir. He now plays golf well enough "that I don't embarrass myself". Wareham has been married for 30 years and has two children.

When Wareham became Vice President of Beckman's Diagnostic Systems Group under the SmithKline Beckman umbrella in 1984, it was, as Wareham puts it, "not in an expansive mode." In fact, the Diagnostic Systems Group did not have a renewal product for their main market, was losing business and was strategically threatened. Wareham immediately set to work to redirect the company, focusing on the core market, trimming away businesses and projects that were dissipating internal resources, and redesigning internal processes. In 1993, Beckman merged elements of its Bioanalytical Systems Group and Diagnostic Systems Group into a single unit, and implemented a planned reduction of 800 employee positions worldwide. And the retooling is continuing even today. Beckman Instruments, Inc ., with just under one billion dollars in annual sales revenue, had sales of over 500 million dollars in clinical chemistry and rapid diagnostics in 1994. The company began a restructuring process in 1993 that reduced operating expenses by approximately ten percent. Recent acquisitions will expand the size of the diagnostic business by twenty percent, adding both critical mass and strategic competencies to the core businesses. In the following interview, Wareham talks about how Beckman turned it around, and what he sees for the future.

Bauer: Many successful managers develop certain business tenets that work for them time after time. What tenets have you relied on in business situations?

Wareham: First, do a few things, but do them right. That means you have to make a lot of decisions of what not to do. I think there are always opportunities in those things you know well and can do well. But I think there are always just as many opportunities to hurt yourself by trying to do too much, knowing too little. Another thing I think is important is what I call "intelligent determination", which is really just good feedback loops to the marketplace and to the customers. It pays to find out what customers are thinking while they're still willing to buy your product, and not just when they stop buying. Another principle is to make sure that what you do with your investments will make a difference. I'm a firm believer in high market shares by designing products for major markets, and that you make sure that they're major products and major opportunities. It's important that you focus on a few things and get high market shares. But if your product line is stretched out like a week's laundry then I think you're going to end up with a profitability problem. I think that major market segments, high market shares, are the drivers. The last tenet isn't as philosophical: it's to avoid the "hoola-hoop" syndrome, falling for a short-term fad that has so much said about it that it appears to be a long-term trend. I think everybody in the industry has gotten caught up in that at one time or another. Formalizing your market intelligence to ensure that you're working with a trend and not a fad is an important tenet.

Bauer: When you took the helm of Beckman's Diagnostic Systems Group in 1984, it was a difficult time for the company. Competitors were targeting your aging ASTRA instruments, profitability was low and the company's replacement products were late. You made a lot of changes in the way Beckman did business, and you're still making changes. What changes

have you made, and what effects did they have?

Wareham: Clearly, I felt we needed to work more on our core business, and that we needed to stop dissipating our efforts in too many directions. We needed to focus on a market segment that didn't have a global leader, then set our sights on having a major share of that segment. There were several things we did to achieve that. To start with, we had to forge the mindset that we would retake our position as an innovator in the industry. Dr. Arnold Beckman, the founder of Beckman Instruments invented the first pH meter, and developed the quartz spectrophotometer, which revolutionized chemical analysis. Later, the company created the innovative ASTRA STAT Chemistry System. So we felt we had a good historical foundation for again being an innovator in the industry. First, we focused our new product resources on a very few things, and in a market we knew fairly well. We stopped a lot of projects, and we sold several business units. Some were in chemistry, and some weren't. It was a variety of things. One that comes to mind is MicroMedia, which we sold in 1985. [Editor's note: MicroMedia was a manufacturer of micro biology products for bacterial identification and bacterial antibiotic sensitivity.] It wasn't part of our core business, we didn't understand it well, and we felt the technologies at McDonnell Douglas' Vitek and the market dominance of Baxter's Microscan made this market undesirable. For similar reasons we divested our Laboratory Information Systems business in 1986. A second thing we did was focus on new market segments. We saw random access chemistry analyzers as one of those new segments. Random access automation was threatening to displace the STAT and routine chemistry market segments, which were discrete segments at that time, but it was without a clear industry leader, at least a clear global leader. Third, we changed the way we used internal resources. We had become a little too decentralized, to the point where we weren't coordinating our efforts. Very little was formalized. In program management, for example, we were spending too much time and money supporting existing products and not enough time developing new ones, so we redefined the program management concept to de-emphasize or eliminate the support function. Basically, were trying to move product support out of R&D. We spent a lot of time formalizing our processes. We documented them for the first time. It took quite a bit of effort and was seen as bureaucratic but it was important for people to know what was expected of them. We formalized our market research. We formalized our product development approach. We took down a lot of internal organizational walls that had grown up over time, which allowed us to implement a lot of multi-functional teams. In the late 1980's we implemented project management for our development organization. What all this let us do was to combine the separate pieces of Beckman Diagnostics into a single system. We were pretty good at a lot of things, and we thought we could really make a difference. It wasn't just engineering, it was software, where we had some competencies and which we were building up at the time, and chemistry, which had traditionally been in the general purpose reagent business, but not in the systems reagent business, with the exception of ASTRA. We took these competencies and applied them to the system.

More recently, we've combined competencies from our Bioanalytical Systems Group and Diagnostic Systems Group. Some employees have called it a merger. I'm not sure I'd describe it as a merger. We have taken advantage of scale in some functional areas, but we have determinedly kept the customer focus at the front end of the business. So for the most part we still have separate thrusts in the major markets, including separate customer support groups and separate service organizations. We have leveraged other centralized support services: order processing, billing, manufacturing, staff support services. In some country markets where we don't have the scale we do have combined organizations, but even there we tend to have separate sales forces. We're least combined today in the U.S., with more consolidation in Europe, and we're most consolidated in the Far East. Our new approaches let us plan more deliberately for the future. For example, we were able to sequence our new product introductions to take advantage of market trends. We introduced the CX3 first to "catch the wave" of DRG driven test paneling, then moved on to the random access analyzers, the CX5 and the CX7, to capitalize on the developing random access market segment.

Bauer: In May, Beckman bought Genomyx, in August optioned rights to Biocircuits Immunoassay technology, and in September announced its planned acquisition of Eli Lilly's Hybritech. You've been very active in this area. Do you feel that it's a buyer's market for diagnostic properties?

Wareham: Immediately, Hybritech is an expansion of our rapid test business. They have a good franchise to complement our core business in fecal occult blood testing. In the long term, Hybritech also gives us life science and regulatory capabilities that we feel are critical to the continued success of our core chemistry business. We know there are a lot more opportunities for acquisitions and alliances that can supplement our internal efforts. There are more of them today than there have been in the eleven years that I've been in the industry. I've heard comments that potential acquisitions are undervalued. I wouldn't say that, but I think the reality of how you make money in this market has finally hit the players in the market. I think that's allowed more opportunities to become available. So I think the prices for acquisitions have come down a little bit. I wouldn't call them undervalued.

Bauer: As you look back on your 11 years in diagnostics, what do you feel were the most significant environmental shifts in the industry? And what do you think will drive us going forward?

Wareham: Well, it started with the DRGs, which drove a lot of the changes that have happened since. Because of DRGs, hospitals are driven by patient throughput, which in turn creates a need for more and faster testing. Random access was a major shift, because it redefined the clinical chemistry market. Workstation consolidation will likely do the same. In the future, physicians will be ordering more specific panels, and that will, in turn, drive work station consolidation. Another big shift has been the increasing globalization of the marketplace. For example, European and Japanese laboratories have been labor reduction insensitive in the past. We've been seeing it start to change for the last three years or so, and it's

continuing today. In the future, I think there will be more focus on managing the entire process of patient care, what's called now "disease state management." Also, I think there will be more consolidation of individual laboratories into larger laboratories, to get economies of scale. Point of care technology may be another big mover of the future. But it's going to have to be economical, because there are other ways of doing the same thing. The economics have to be balanced with the opportunity. Something that's very important, is that the industry is becoming an industry. I would look for signs of us having uniform initiatives for the benefit of our customers and for the benefit of our customer's patients. And I think we're getting close. That's a lot different from where we were ten years ago.

CaseBauer
Business Development and Research

An Executive Interview with Jean Luc Belingard, President of Roche's Diagnostic Businesses

Diagnostic Insight, 1997 Interview

On May 24, 1997, Roche agreed to purchase the outstanding shares of Boehringer Mannheim for $11 billion (US). This is the largest diagnostics acquisition in history, and Roche's largest acquisition since its inception 100 years ago. The acquisition includes Boehringer's pharmaceutical and diagnostics divisions, and DePuy, an orthopedic products business owned by the company. These businesses together, combined for annual sales of $3.50 billion in 1996. Roche's reported sales in 1996 of $12 billion.

The merger of the diagnostics businesses of Roche and Boehringer Mannheim will create a $2.90 billion diagnostics division employing 13,500 and rivaling Abbott for the number one position in the industry. Prior to the acquisition, Roche's diagnostic business was $0.55 billion.

In addition to diagnostics, the acquisition includes Boehringer Mannheim's pharmaceutical business, which posted sales of $1.2 billion in 1996, and which will improves Roche's share in the global pharmaceuticals market share from 2.7% to 3.3%. The acquisition will give Roche a strong marketing/sales position in Europe, particularly Germany where Roche will become the third largest pharmaceutical company. Additionally, Boehringer Mannheim's newly launched cardiovascular, metabolic and oncology products, as well as their research and treatment for osteoporosis, will complement the Roche product portfolio.

Roche also acquired Boehringer's interest in the DePuy Group, one of the world's leading manufacturers of artificial joints and orthopedic products. In 1996 DePuy employed 2,900 people and posted sales of $700 million. DePuy's products range from artificial joints and implants to orthopedic instruments and arthroscopic equipment covering the areas of joint replacement, fracture stabilization and sports medicine. DePuy will continue to operate as an independent company. The 15.8% of DePuy shares not held by Boehringer are traded on the New York Stock exchange.

At this years annual AACC meeting in Atlanta, Jean Luc Belingard, head of Roche's Diagnostics Division, chatted with Robert Bauer, President of CaseBauer and Associates about changes within the company, the effect they will have in terms of the diagnostics industry, and the direction the new division and the industry will take in the future.

Bauer: Roche has significantly changed the profile of its laboratory business portfolio, divesting its interest in Roche Biomedical Labs and expanding its interests in IVD. Can you tell us what drove this fundamental change?

Belingard: We merged Roche Biomedical Labs with National Health Laboratories to create the number-one commercial lab in the US, Lab Corp. of America. Lab Corp. will be a $1.7 billion company this year. It is our intent to make sure that whatever we own is positioned favorably in the market. Lab Corp. has the biggest volume of testing every day, and is in a position to achieve the lowest cost position in the industry. Lab Corp. is streamlining its operation, leveraging synergies between the two companies, and reducing from 36 regional labs to 24; shaving $130 from operating costs. At Roche, we feel that it is much better to own 49.9 percent of the number-one organization than 100% of a number-four that is not positioned to be competitive in the long term. There is no question that we see the merger as a step forward.

Bauer: Has the relationship of Roche Diagnostics to the commercial lab business changed since this change in ownership?

Belingard: We have not changed the relationship significantly because historically we have always made sure that the lab service group of Roche would stand on its own feet in terms of being profitable. In effect, we are managing RBL as before.

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Bauer: There was some surprise in the industry that Roche made a diagnostic acquisition rather than a pharmaceutical acquisition. What was the thinking behind that?

Belingard: Roche is not a pharmaceutical company -- it is a health care company. We have pharmaceuticals, diagnostics, chemicals. We did not buy just a diagnostics company -- we bought a health care company. Boehringer Mannheim is in pharmaceuticals, diagnostics, hip replacement. We perceived the acquisition as strengthening Roche as a health care company. You can say that Boehringer Mannheim is a bigger diagnostics company than a pharmaceutical company, but it just happens to be that way.

What we've done is strengthen Roche's overall position in terms of being the leading health care company; as a result of that, we end up being number one in diagnostics. We bought $1.5 billion in pharmaceutical sales as well, with some very promising pipeline products in pharmaceuticals. I have read with interest that we are making a diagnostic acquisition, but it is not the case at all -- we invested in health care.

Bauer: Will Roche expand its interest in diagnostics with additional acquisitions?

Belingard: I don't know. We are in pharmaceuticals, diagnostics, chemicals -- we want to be a leader in each of those pillars of Roche. Our goal is to be number one in each segment we're in. If to remain number one it takes some more acquisitions, why not? We are very flexible, very open -- and we certainly do what we have to do to maintain the position. I cannot say that we have specific targets as we speak, but we like to make sure that in term of our ranking, in terms of the breadth and depth of our portfolio of technologies, we have a leading position.

Bauer: There has been a lot consolidation in the diagnostics industry. What do you think are the key componenants for a successful company in this environment?

Belingard: We perceive the diagnostics trend to be toward a type of polarization. We will have the small niche players which are going to be mostly technology based, GenProbe is an example. Then we will have the global players--Abbott, Roche-Boehringer, and to some extent Johnson & Johnson and Dade Behring. You will see more consolidation, and I think that the people who remain in the medium sized will have a problem in terms of competing in the long term.

Bauer: When you look at the industry overall, there's a lot of speculation on how much the industry will ultimately consolidate. There are still a number of large companies that hold the potential for acquisition. Do you have a vision of how the industry will look some years in the future?

Belingard: There are years of capacity in the market--it's a vast market. That kind of capacity will have to go away. As long as you see over-capacity, you will see consolidation. There are 30 or 50 immunoassay systems on the floor--how many do we need? Two or three?

The diagnostics industry is not normalized; it is losing money and does not have a fighting chance for the future. I expect the consolidation to be pretty brutal. I think that we are in for some extremely aggressive consolidation. I think there will pretty aggressive consolidation the five years to come and by the turn of the century we will stay with four or five global players and a lot of small niche players.

Bauer: How do you think the companies will ultimately end up competing against each other? Historically, one company has stood out in a particular area. Behring in proteins or Abbott in immunoassay.

Belingard: The company dominating one specific segment is passé. Dominant, focused positions is going to go away. You will have people with 15% of the global market--you will have three or five of these unless you can institute a strategy of consolidation across segments. Business segmentation on the basis of technology will go away.

Bauer: Some analysts say that the diagnostic industry is not very healthy from a competitive point of view--that companies are overly aggressive in discounting products. Could you compare and contrast the competitive atmosphere in the diagnostic industry vs. that in the pharmaceutical industry?

Belingard: I think it's a matter of providing value. If you offer generics, you may have a pricing problem but if you offer value you can charge more. Our dedication is research--innovation based business, so we can charge fair pricing.

Bauer: Roche's investment in PCR was certainly one of the most significant investments made in the diagnostic industry in recent history. What are some of the lessons to be learned from that experience?

Belingard: When you invest in technology, you are rarely wrong. When we bought PCR, for 300 million dollars, everyone thought it was crazy, but now it is a very fruitful, profitable products business. Today, including the acquisition price, it still is very profitable.

Some of the difficult parts of that business? Turning a scientific idea into an everyday, practical product that customers can use is a big challenge. Consumers don't understand the role of industry. They think what matters is that someone invented PCR. Kerry Mullis's idea is a great one--he won the Nobel Prize for it. But the rest is turning what Kerry Mullis invented into a product that can be manufactured in an industrial process that can be repeated on a cost-effective and regular basis. That is as big a challenge as inventing the technology. That's what industry does--it brings value to the customer.

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D-Day for Abbott

In Vivo, December 1999, Vol. 17, No. 11, p. 3-7

January 10 is D-Day for Abbott Laboratories Inc. to pull 125 diagnostics tests off the market as part of its consent decree with the FDA (See "Abbott Gets into Hot Water, " IN VIVO November 1999). The decree, which follows the FDA's accusation that Abbott used shoddy manufacturing processes in its main US-based manufacturing plants, is unprecedented—and hurts far more than Abbott alone.

Given that Abbott controls 40-50% of the immunoassay market world wide, the decree places a significant burden on customers. According to a survey of 75 hospital laboratory directors conducted by the consulting firm CaseBauer & Associates, test turnaround time, training, use of equipment, and budgets will all be hurt by the consent decree. So to what extent can competitors benefit?

CaseBauer believes, based on the mood of the participants, that the problems could affect Abbott's long term position in the in vitro diagnostics market, where it is a preeminent player. Laboratories have no choice but to shift assays to alternate analyzers or products, either by increasing use of existing non-Abbott instruments, buying or leasing alternative instruments, or sending tests to outside reference labs. Of tests being shifted, the survey found half are going to analyzers already in place, and half are going to newly acquired or borrowed analyzers. Only a small number of labs have been able to stock up on supplies in the hopes of weathering the storm. Forty percent of participants said that changing products will have an impact on the clinical values and critical ranges reported to physicians and will require doctors to be re-educated as to the meaning of tests. Another 30% anticipate they will have to re-program their laboratory information systems. On average, laboratories expect to spend more than $17,500 to work through this situation, with the biggest expense for retraining.

In the short-term, STAT assays—those that require quick turnaround times —will have to be moved to slower back-up analyzers and more tests will be sent to outside reference laboratories. In addition, laboratories will start to use non-Abbott assays as alternatives to IMx and AxSYM assays. Recognizing the need to have a "critical mass" of tests on an analyzer, 17% of IMx / AxSYM users, and 15% of TDx/ TDx Flex users expect to replace other Abbott tests —that is, those not impacted directly by the consent decree —with tests made by an alternate supplier. TestPack rapid tests are also being replaced by alternate products, either from Abbott or competitors, but users are less likely to switch from Abbott for additional assays because alternatives are higher priced.

Abbott has been very accommodating to its priority accounts, less so to others, CaseBauer points out. Many laboratories say that in the future they will reduce their vulnerability to this kind of setback by not putting all of their eggs in one basket. And laboratories that are being rescued by new suppliers feel an obligation to stay with that supplier and even broaden the test menu. Says one director in the Southeast, "once we bring the Diagnostic Products Corp. (DPC) instrument in, we have to bring on other assays to cost justify it."

More than 71% of the labs surveyed say they are undecided and open to alternative suppliers for long-term products. Twenty-four percent remain committed to Abbott and will switch back when its products become available again. Another 5% are fed up and are unsure of what they will do.

According to CaseBauer, Bayer AG appears to be the largest beneficiary of heterogeneous brand switching, with 42% willing to use a Bayer's ACS:180, Centaur or Bayer Immuno 1 already in place. There is no clear leader for labs planning to acquire new analyzers. More than three-quarters of TestPack uses are planning to buy a new rapid test, although 58% have not decided on a specific alter native. Some are considering substitute products offered by Abbott, such as Signify hCG. Of those looking at new products, 58% report that they have not decided on a specific alternative. If anyone benefits here, it is likely to be tiny Quidel Corp., which offers a competitive product. For Abbott, the diagnostics problems extend far beyond its testing business. As Abbott stock, in part thanks to its diagnostics troubles, has drifted down some 30% in the past eight

months, its new management's attempts to transform its business have been slowed dramatically. Two of the biggest examples: the diagnostics problems contributed to the months-long delay in closing the acquisition of femoral artery closure device manufacturer Perclose Inc. and stalled movement on its acquisition of Alza Corp., which eventually fell apart for antitrust reasons.

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Business Development and Research

Who Stands to Win the IVD Price Wars?

Diagnostic Insight, Spring 1996, Vol. 23, No. 2, p.p. 6

DIAGNOSTIC INSIGHT extends its appreciation to CaseBauer and Associates, Dallas, Texas for the design and implementation of this reader survey.

According to the results of the most recent DI survey, eighty-eight percent of readers do not think the IVD industry is handling price pressures well. More than a third of reader respondents characterize the situation as a highly aggressive or dangerously aggressive price war. According to Kevin Keene of Beckman Instruments, "the greatest threat to IVD companies is other IVD companies and their pricing practices". Frank Smith of Liston Scientific agrees: "If you look at the profit picture of the industry, even for the major manufacturers, it seems that they are lowering prices unnecessarily —one company lowered its prices under "customer pressure", and other companies just followed suit. Buyers have gone beyond getting a good price; they are spoiled."

Expanding on their survey response, several readers noted that other pricing pressures can be attributed to the growth of both managed care and large group purchasers, such as national hospital chains. Lower levels of reimbursement, such as the pending 25% reduction of Medicare laboratory fees and the proposed 7 year rate freeze, exacerbate the pressure on clinical laboratories, and in turn, on IVD suppliers. It is interesting to see, that while Medicare reform is addressing laboratory fees, specifically, most readers feel that the impact of the Medicare reductions will be hardest on IVD manufacturers whose products represent only a small portion of laboratory costs. Smith of Liston Scientific says that "ultimately anything that takes away lab reimbursement hurts us."

Hey! It's not my fault.

Readers often see their competitors as bigger contributors to the price war than themselves. Fifty-three per cent feel their competitors were more culpable in the price war.

One reader termed the industry "reactionary" right now, because of pressure coming from the customer side. "The immediate reaction is just to drop prices. It's forcing price drops, which are reducing margins, which in turn are reducing investments." One prominent laboratory buyer in a large metropolitan hospital countered, "the manufacturers are easy... put up a little resistance and they drop price... it amazes me". His comments "for obvious reasons" were on the condition of anonymity. Some buyers are adding to the current confusion of the IVD industry, because of con fusion stemming from their own evolving organizations. "Buyers themselves have difficulty figuring out who is responsible for purchasing decisions, and there are obviously conflicting opinions about what products to buy and which are necessary for the institution," says one reader, who works for a large manufacturer. "We have seen hospitals fusing together, although these are divergent entities —for instance, some hospitals may be in affluent areas, merging with very large, metropolitan hospitals that have totally different patient profiles, needs, and reimbursement procedures. " While immunoassays have been a little more protected from price spirals, one reader says, the larger clinical chemistry companies get into the business and immediately go into a price cutting mode. "I don't think that benefits the industry," he says. A Hycor Biomedical reader noted that "chemistry has seen some of the worst self-destructive pricing behavior."

Winning the battle and losing the war?

Cutting product costs won't significantly cut overall health care costs, readers say. "The operating expense problems for laboratories are not a materials cost issue," says Larry Worden of CaseBauer and Associates, "the real issue is overutilization of tests by physicians and laboratory labor inefficiencies. If, as an industry, we get too caught up in the belief that laboratory materials costs are the central issue, we will hasten the "commoditization" of IVDs and radically shift the basis of competition in a direction most manufacturers are trying to avoid". Many new arrangements have arisen in order to

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cope with the changing market place–consolidation among firms as well as partnerships within the industry, which have helped many companies to gain footholds where a single firm might otherwise fail. A trend toward volume selling arrangements has arisen, also. However, Tim Montgomery of Boehringer Mannheim Diagnostics says, "A company that offers a bulk package of several different tests or products can be confusing. On the heavy-use products, the company might offer extremely competitive prices, but on less frequently used tests, these might be more the 'bread and butter.' The precise tests chosen vary according to each institution".

Loss leader pricing strategies are becoming the rage. "IVD manufacturers may be over focusing on price and driving the commoditization of their own products," an impression shaped by several readers. One manufacturing executive described a situation in which one manufacturer cut prices on specific products way below costs to "drive another manufacturer out", with the anticipation of profiting on other products. "The simple fact is that laboratorians want a whole lot more from IVD manufacturers than price concessions," says Worden "since they don't see a trade-off they have come to expect it all. Laboratorians generally have the perception that the industry is very profitable and could do more".

One reader, who works for a large manufacturer, says that he has heard that the actual contribution to costs of all laboratory instruments, reagents, and supplies is something like 1-2%. "Even if we gave it all away for free, it would not significantly reduce national health care expenditures," he says. Defensive medicine is a problem, because physicians cover themselves for fear of malpractice suits, which in turn brings the laboratory industry under fire for overutilization; labor is also a consideration when looking for substantial cost savings, he adds. "Material costs have very little to do with the laboratory," Smith says. "In my opinion, the problem with health care costs is primarily administrative and also due to fraud and abuse in the system [commercial laboratories]; it's non-medical factors that need to be brought under control."

Added-value services are also aggravating the situation. Currently, IVD customers expect the industry to sell instruments and reagents at low cost, supply someone to install it and run crossover studies. "All of these value-added services have significantly eroded any profits that used to be there," Smith says, "No one manufacturer can take a stand and say, 'Look, Mr. Customer, you have to reassume some responsibility for the things you used to do when you bought the product. "

Are we communicating?

More than one reader suggested that BMA could play a role in an initiative to slow the price war, as a collective voice for the industry. A couple of diagnostics industry representatives said that their firms are trying not to cave into pricing pressures, and have made a real effort to hold prices steady. Another said that his company, recently purchased, had struggled to maintain price, but says he expects that could change under new ownership. The fundamental question is whether the industry believes laboratory tests and technology have any value and are communicating it. "It amazes me to continue to hear how many laboratorians feel there are high profits in the IVD business," Worden says. "Laboratorians anticipate a continued stream of new products and technologies with little understanding of the financial structure of their suppliers... and manufacturers are doing little to change this perception."

And the winners are?

One employee at a Big Three lab says that if the Medicare cuts are enacted the way they are now, this represents a "disproportionate hit" on the laboratory industry, but says that the target of Medicare savings may yet be lowered, yielding some relief to labs. "Providers may stand to gain from a lowering of that ($270 billion target), because the administration continues to say that providers are being hit too hard and too fast, which could impair the quality of services."

Diagnostic Insight readers (81%) were not "very familiar" with pending federal budget projections for the Medicare program, provisions that could severely limit reimbursement to clinical laboratories, and ultimately hurt IVD manufacturers. A House-Senate conference committee recently rejected policies that would provide some relief to the laboratory industry. The biggest loss: some $6 billion in lab fees will be saved by the government in the form of a freeze on lab fees from 1996 to 2002 and a reduction on fee caps to 65% of the national median lab fees, beginning in 1997. Labs were also disappointed by the failure of Congress to include national all payer direct billing rules and uniform lab coverage and payment policies in the budget package. These provisions had been promised in return for the deep Medicare cuts, which could amount to a total of $270 billion over seven years. Readers feel that the impact of the cuts will be harder on IVD manufacturers than on clinical laboratories. "When ever there is confusion in the industry, it hurts the manufacturer. " Frank Fallin of DuPont Diagnostics says his buyers are already using the proposed Medicare cuts as a negotiating point on which to gain still lower prices. If, in the end, however, manufacturers drive commoditization and laboratories end up with reduced materials expense but significantly reduce their new product and service stream–who will have won?

CASEBAUER
Business Development and Research

An Executive Interview with Richard Barker, President and Chief Executive of Chiron's Diagnostics Business

Diagnostic Insight, 1998 Interview

Richard Barker, who was raised in the suburbs of London, holds an Oxford undergraduate degree in chemistry and a doctorate from that institution in biophysics, with a specialty in magnetic resonance. He began his career in the oil industry and later joined McKinsey, a management consulting firm, where he worked for 13 years, advancing to the position of European practice leader for health care. During his career, he has worked in Asia and most of Europe as well as in the United States. He joined IBM about four years ago, heading its Health Care Solutions business —the sales, marketing, and solution-development activities of IBM in the worldwide health care sector. The business encompassed everything IBM supplied to the sector, from mainframe computers to consulting services and network technology. Key to his role at IBM was developing health-care-specific information solutions, including data networking and voice recognition systems for radiologists. Barker joined Chiron in mid-1996 as president of the corporation's diagnostics business, providing him with an opportunity to lead an enterprise engaged in research, development, manufacturing, marketing, and sales in a wide range of technologies. In running this business, he practices a principle honed at IBM—the importance of creating solutions for customer problems, not simply supplying customers with hardware. "If you think about it, that's what a diagnostic system is -- a health care information solution," Barker explained. "I believe strongly that we need to move our company from being just a very fine product company to one that provides our customers with solutions —solutions that really solve problems rather than simply represent technology breakthroughs," he said. Barker indicated that his organization must also shift in emphasis from selling effectively to a wide range of customers to securing long-term relationships, particularly with its large diversified customers. "I want to create a high-performance organization where the best people are attracted and we advance their careers in exciting ways, and where we encourage people to think globally," he said. "There aren't many organizations —either US or European —that truly think globally, and one of the challenges for my first year at Chiron was to encourage everyone to think of all markets when designing marketing programs and products, rather than thinking from the US outwards." Barker, who lives in Boston, has three grown children living in the United Kingdom —two out of college and one preparing to attend. When he's not on the job, Barker enjoys outdoor activities such as trekking up mountains, kayaking, skiing, and traveling. Besides his responsibilities at Chiron, he has a directorship on a health care information systems company board and is involved in two Massachusetts industry associations. Here, Barker talks about Chiron's upcoming plans as well as happenings within the diagnostic industry.

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Bauer: As the second largest Biotechnology company behind Amgen, Chiron has a very different business profile with fairly large investments in non-therapeutic products. What is Chiron's general strategy, and how does diagnostics fits into it?

Barker: Ours is a tripartheid strategy, which looks at therapeutics, prevention products such as vaccines, and diagnostics to manage particular disease states. We believe that being involved in all three areas for particular disease states brings us strength that we would not have in just one area. Because we are a science-driven organization, we focus on areas such as infectious and viral diseases, oncology, and cardiology, therefore getting some scientific synergy by incorporating preventative, diagnostic, and therapeutic approaches to the diseases. For example, with Hepatitis C, we are working in all of those areas to tackle a disease that in fact Chiron was the first to identify -- the non-A, non-B Hepatitis C. Linking the tripartheid logic to basic science holds the three businesses together.

I think that in the past Chiron has sometimes spread its wings too far. In the vision products business, for example, which we sold in late October, we believed that our science would give us some advantage, but in fact it was not a reason to be in that downstream, broad-based business. Recognizing that, we sold it. We are trimming the portfolio, but the core of the portfolio is involvement in diagnostics, vaccines, and therapeutics.

Bauer: Are there other significant synergies other than R & D to be realized from this approach?

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Barker: Yes. There are some particular synergies at the sales level. For instance, when we call on HIV physicians we can talk to them about the potential of some of our immunological therapeutics and diagnostic products. When we call on oncologists we can talk about bone and breast cancer markers that we make diagnostically as well as the Arida™anti-cancer drug that we market on behalf of Novartis. We can also build a common global infrastructure to support a series of businesses. We have a substantial diagnostics business in Japan -- it makes it that much easier to jump-start our new products in other areas.

Bauer: Chiron's Branched DNA probe products are selling at an annualized run rate in excess of $50 million and sales almost doubled from the first to second quarter 1997. There's a lot of discussion in the industry about the sensitivity advantages of amplified probes vs. the practical advantages of the non-amplified probes. How does Chiron see this market evolving?

Barker: I believe that we have seen a lot of evolution in technologies for the detection of viruses using DNA and RNA -- and we'll see a lot more evolution. With our DNA technology, we have taken the sensitivity from 10,000 viral copies to our new product that will arrive early in the new year with the ability to detect 20,000-50,000 copies. At the same time, PCR and target amplification have advanced rapidly and Roche has invested very heavily in that process.

If I look ahead, we will need both technologies in one form or another and we will need them in ways that can be readily automated to take the labor intensity out of processes of viral load and other gene probe measurements. Many would like to believe that it's the underlying chemistry that's important, but in fact, users usually don't care about that -- they want an accurate result quickly. The winning companies will be the ones that are there first with a well-automated, user-friendly, information-integrated solution -- and that's where we're putting our investments.

Bauer: Chiron's new Centaur™System is a major advance for the company in immunoassay automation. This market segment has historically been Abbott's stronghold. What are the keys to competing against Abbott in the long term?

Barker: The Centaur will be the highest-throughput, most automated immunoassay system that exists. It will take immunoassay into the same level of automation as chemistry. I think it's a major step forward in that respect. We've placed some instruments with customers, and the high-throughput laboratories already are very enthusiastic about both the throughput and the potential breadth of menu. Competing against Abbott requires us to be fast, because we believe we have a lead on the new generation of Abbott instruments -- the Architect line. We'll also build on the reputation that Chiron, and Ciba-Corning before it, had for great, solid customer relationships and quality instrumentation, as well as high levels of technical support and service.

Customers in immunodiagnostics want a choice -- they don't want to have only one place to go for the core of their immunodiagnostic needs. With the Centaur™not only do they have a choice, but they have a choice of capabilities not available anywhere else.

Bauer: Chiron has a significant business in Point of Care and continues to invest with products like RapidLink™Information Systems. Yet, the company sold its interest in the Biotrack coagulation product line a couple of years ago. What's your opinion of the coagulation point of care market?

Barker: The company learned a lot from its former investment in Biotrack. It learned the key differences that exist between point-of-care markets and laboratory markets in terms of who the customers are, what they want, and the kinds of people needed to market these products. I don't think we will make the same mistake twice. We are bringing critical care specialists into our Rapid Link and Rapid Point marketing programs so we can relate as well to the clinical decision makers as we have to the laboratory decision makers.

The trick is not taking just anything to point of care -- the trick is taking those analytes that have real time differentiation, real urgency. We've already begun blood gases, sodium potassium, blood electrolytes, metabolites like lactate and glucose. But close behind those we have cardiac markers; when someone presents in the emergency room with chest pain, it's time critical to know whether the person has had a heart attack or bad indigestion. We'll be bringing to market instruments with the capability to assess that. I also think there will be other coagulation-based tests.

Bauer: Chiron has been very active in the area of therametrics, using a diagnostics as a metric for the selection of patients, the management of the course of treatment, and so on. Where do you think we'll see initial breakthroughs in "therametrics?

Barker: We've had minor breakthroughs -- viruses and cancer markers that were discovered. I think the next major breakthrough will come in two principal areas. The first is taking some of the established technologies to the point of care, so that physicians get responses within minutes or even seconds rather than sending tests to labs overnight. This will be gated by the readiness of physicians and other clinical staff to use such instruments on an ongoing basis. We're investing heavily in this with our rapid point-of-care instrument.

The second major area is opening the potential of genomic technology in diagnostics. We are already beginning to see very

exciting markers emerge that compare, side by side, the genetic and biochemical situation in a tumor vs. normal tissue of the same type. You get a lot of very rich information that will lead inevitably to new markers that will enable us to identify cancers earlier in the course of disease.

Bauer: Will thera-metrics emerge as a way to differentiate or direct therapy toward specific drugs?

Barker: Absolutely. I think there is substance behind the idea of pharmacogenetics. I don't have any doubt that we are going to be able to pinpoint the use of certain drugs because of information that we get on the genetic patent and predisposition of patients. It may be five years before we have a lot of impact to this but I think it will be relatively soon.

Bauer: Chiron's product lines are investment and capital intensive. As an organization, how do you keep from diluting your investments?

Barker: All of our businesses are investment-intensive, and the diagnostics business is capital-intensive, because we not only have to design and build major pieces of capital equipment but also finance them in the hands of customers under the reagent rental agreement. I think that requires us to increasingly focus our future product-development activities -- whether that be a chemical entity or a diagnostic system. We are in the process of refining our R & D portfolio to accomplish that. Chiron spends more than $400 million a year on R & D, a ratio that few other companies have been able to sustain. We're seeking to concentrate on areas of real differentiation -- in diagnostics, that means being leaders in automated viral load measurement; particular infectious, oncology, and cardiac panels in immunodiagnostics; and specific point-of-care systems in our critical care arena.

Bauer: One of the notable points about Chiron is that it has a number of different pathways into the diagnostics market -- partnerships with Ortho, direct product distribution, and now a POL distribution agreement with Polestar. What would you say is Chiron's distribution philosophy?

Barker: Within the diagnostics business it is to take market-leading products to market ourselves. But what is needed to do that is changing around the world: customers are consolidating, major buying groups are emerging, regional health systems are beginning to dominate the U.S. marketplace. Increasingly, taking products to market ourselves means building relationships with these very large health care institutions in an account-management method. Over time, it will become less and less important to have a very large sales force calling on all of the potential outlets. We are in the process of transitioning to a more concentrated model of what marketing is about in diagnostics.

I'd say we are a direct sales organization, but from time to time it's sensible for us to have somebody else take a product to market. When the Ortho / J & J joint business that we have in blood screening was created in 1989, Chiron didn't have its own diagnostics organization of any scale so it made sense to partner with J & J. The next time we're in a situation such as that it may make more sense to take that product to market ourselves.

Bauer: With the recent Beckman-Coulter, Roche-BMC acquisitions, the market leaders are getting bigger, but we don't see a lot of reduction in industry capacity. We still have the same number of major competitors in chemistry, hematology, and other areas, and profit margins are reasonably tight. Where do you see the industry going from here?

Barker: There will be a small handful of broad-line majors in diagnostics, and we intend to be one of those. There will be the constant creation of new diagnostic companies that will bring particular markers or point-of-care products to market. There may not be a decrease in the number of total diagnostics companies, but I think at the high investment-intensive end we've seem quite a rapid concentration. Although there may still be a lot of instruments out there, over time a Dade-Behring will have only one chemistry instrument, a Roche-Boehringer will have one narrow line of chemistry instruments. But unfortunately, if you have commoditized a segment, it is very difficult to ' decommoditize' it. In chemistry the plan has been very effective in reducing costs to a few cents per test, which is great for the customers but not that good for return on investment. The trick is to have scale but to focus your R & D investments on areas of uniqueness or differentiation, and that's what Chiron is seeking to do.

Bauer: Some recent acquisitions have brought diagnostic and pharmaceutical businesses together. It wasn't that long ago that we saw pharmaceutical companies getting out of their diagnostic interests. Are there benefits to pharmaceutical and diagnostics companies joining forces?

Barker: This synergy between diagnostics and therapeutics is now becoming a reality, so pharmaceutical companies are saying, ' We need access to the diagnostics business.' Some of them do that very selectively, by individual agreement for particular products; some have done it in a fairly wholehearted way, such as Roche's acquisition of Boehringer Mannheim. The dilemma is that if you buy a very large diagnostics company, you buy a lot of capital-investment needs and a commercial infrastructure that is different than the therapeutic infrastructure. Therefore, you're buying a lot for the therametric concept but I believe it is a move in the right direction that should result, over time, in a more specialist, higher-value-added mentality in diagnostics.

For too many years, diagnostics companies left to themselves focused almost exclusively on developing broad-menu, high-throughput instrument systems. But that's only a piece of what diagnostics ought to be thinking about -- it should be thinking about the impact of those measurements on the effectiveness and economics of health care. Perhaps in the hands of pharmaceutical companies we'll see that shift, and pharmaceutical companies will be more interested in how the diagnostic guides the process of therapy. Maybe we will see some higher-value products and pricing approaches.

CASEBAUER
Business Development and Research

An Executive Interview with Christian Policard, President of Pasteur Sanofi Diagnostics

Diagnostic Insight, 1997 Interview

Sanofi is a Paris-based multinational company whose core business is health care, including pharmaceuticals, diagnostics, and animal health. Its powerful research and development organization focuses on major therapeutic areas. Sanofi's mission, since 1973, has been to improve the quality of life.

The Sanofi beauty business comprises well-known brands such as Yves Saint Laurent, Van Cleef & Arpels, Roger & Gallet, Krizia, and Fendi and associate companies Nina Ricci and Yves Rocher.

Sanofi employs 37,500 men and women in more than 100 countries, with a global economic presence amounting to FRF 41.3 billion and products with leading positions in world markets.

In the following interview, Pasteur Sanofi Diagnostics chairman Christian Policard provides insight on his view of the IVD market.

Bauer: With the ACCESS® automated immunoassay system, Sanofi jumped right in the middle of a crowded and competitive immunoassay systems market. What is your assessment of your situation today?

Policard: Many companies invested in the automated immunoassay market at the same time. The fact is, there are just many too many immunoassay systems on the market today. Profitability is down. Thyroid, TDM and manual products profits are down. Only infectious disease and cancer are holding.

Will this be a profitable market long term? I really don't know.

But what I do know is that market cannot support all the immunoassay manufacturers that entered the market and the market will enter a period of consolidation. I envision this to be very similar to what happen in the clinical chemistry market in the 1980s. The net result will be that three, maybe four primary automated immunoassay competitors will dominate the market.

Abbott is the strongest. Abbott has the large position in the market and is effectively protecting share. Abbott is in position to provide many value added services is even setting a pace of services that others are finding hard to match.

If I look at our strengths and weaknesses, I consider Sanofi to be too small to be effective in North America. A company needs to have economies of scale in order to provide the necessary levels of service in a market that is increasingly demanding more service.

For us to deliver our ACCESS ® system with the type of support that we provide in Europe our cost is almost twice as much.

Now the US market is very important us and it's urgent that we become a stronger player. We will take action to see that happens.

In order to deliver competitive high value services, we're going to need an alliance in the U.S. We cannot go it alone. We need to partner. Someone with an established infrastructure... possibly a clinical chemistry product company.

I strongly prescribe to globalized market and localized management. When it comes to investment resources and research development, centralization is important to leverage the capabilities and bring the necessary resources to bear. At the same time, it must be recognized that every market is unique and that a decentralized operating organization can be most

effective in adapting to specialized regional demands of marketplace.

Bauer: Overall, what is your assessment of the IVD opportunity?

Policard: The IVD market is depressed. Market growth is flat, at best, and testing volumes are decreasing. At one time, Pharmaceutical companies were intrigued by the IVD market. Compared to the pharmaceutical industry, the size was small, but the consistent 15% plus growth was intriguing. This market is no longer growing at that rate and as such, this interest has waned, except for a few companies such as Sanofi.

When I look at the growth opportunities it's hard to envision much growth in the U.S. market. And the situation in Europe is even worse with some markets declining as much as 2-3% in volume and pricing.

In recent times we have seen declines in the IVD market such as 20% in Italy, 6% in France, and 3% in Japan.

There is little opportunity for growth in the established markets.

Bauer: What are the challenges facing IVD companies?

Policard: I would characterize this revolution in the IVD market as very similar to the revolution in Microprocessors. I essentially see many companies looking at the market the same way they did ten years ago. This is a sure formula for failure. I expect these companies will be in big trouble if they do not recognize change and alter their strategies.

The IVD market is changing. One key change is a more demanding buyer. This is largely a function of consolidation of healthcare providers. In the US, groups and chains are consolidating the hospital market. In Europe, the commercial laboratories are consolidating.

The result is fewer customers and larger customers. These “new” customers are exerting extreme price pressure on the market. Hospitals want better prices and they want more free services than ever before.

Essentially, they want to transfer their costs, for training and other product services to the IVD manufacturers. Buying decisions are not being made solely on technology and innovation any more. Services are becoming more and more important. Just look at the growing expectation by hospitals that the manufacturers train the operators and provide, in some cases, both the manpower and the supplies for the product evaluation.

This requirement for free services will drive mergers in the market. If the services must be offered as free, this is the only way to provide them and preserve a bottom line. In a flat market you must leverage service. This means supplying many products to your customer. Manufacturers need a broader fare to be profitable in the environment.

If a company has less than $25K to $30k in business, some buyers will not even meet with them. Manufacturers need critical mass to be competitive.

Another key challenge is regulation. I anticipate that the regulators, and the regulations facing this market will continue to move along the lines of those regulations facing the pharmaceutical industry. What this means is that it will take longer and longer to bring products to market.

There was a time when IVD products could be brought to the market in a matter of one or two months. But as I project the trends I see today, I anticipate that we are rapidly moving towards IVD approval cycles in excess of a year. And this is very troubling to me.

Diagnostic products have a relatively short product life cycle and need to be renewed every one or two years. When you couple this short life cycle with the extended regulatory approval times the situation could become most difficult.

Another key issue is IVD’s manufactures lack of influence on the process of change. IVD is a small industry and has really no effective lobbying power with the exception of maybe Boehringer Mannheim’s efforts in the field of diabetes. What this means to me is that IVD will not be well represented in political decisions and therefore decisions will likely be made that negatively impact the industry in the absence of a strong defending body.

Bauer: Globally, how are these challenges developing?

Policard: Northern Europe is similar to the US... a bit behind but moving in the same direction. Germany leads the pack.

I see significant similarities, particularly in the last 5 years between Japan and Germany. These countries function very

alike. This of course is not very surprising given the German healthcare system was modeled after the Japanese.

Southern Europe, France, Italy, Spain, are socialized and will to stay focused on preserving its employment. In southern Europe, the change will be much less dramatic than in the US and Northern Europe... it will take much longer.

Bauer: Much is being said about privatization in healthcare. What is your outlook for privatization in Europe?

Policard: As I look across the industry I expect that in the U.S., Japan, and the U.K., private concerns will prevail and the government will step out as much as it possibly can from healthcare.

In France, it has not changed much in recent years from its 50%/50% split. I envision in the future that potentially 60% of the testing could be done on the private side and 40% in the public sector, but not much more of a shift than that.

In my opinion, Germany will continue to support a large public sector in healthcare.

Bauer: What will result from the consolidation of testing, or Plateau Technique, as it is referred to here in France?

Policard: In my opinion Plateau Technique is good for testing that is not urgent. Plateau Technique is the answer for cost reductions and it's good for classical tests such as clinical chemistry testing.

At the same time Plateau Technique is not good for cardiovascular testing, tests like Myoglobin and Troponin. For these tests, speed is important and here is where point of care and specialization will play a role.

What I envision happening in the market is that we will ultimately have two basic IVD markets. One which I would characterize as that of industrial automation and another that I would characterize as that as high technology, disease related products.

Now when you look at the market and you realize that there's two types, the industrial and the disease related field, I think you must also realize that it would be extremely difficulty for a company to be successful in both. These market segments require very different skills.

To be successful in the industrial automation, you will need automation, communication systems, information technology and above all, a low cost position. Manufactures will not be successful without leading in 2-3 of these areas.

On the disease state side of the business, I envision many niches or that will offer significant growth opportunity. Essentially in these markets the value of the IVD product will be how well it contributes to the global control of the disease state.

I also believe that the advancement of product systems will have an overall limiting effect on competition. What I mean by this is that as you look at the sophistication of systems in this marketplace, more and more is becoming difficult to pioneer and master all the technologies required to be successful. As such, companies will need to work together to bring products to market, with the exception of a few large companies will have the wherewithal to bring systems to market. Ultimately this will have the effect of limiting competition in general.

Bauer: What does this mean for Sanofi’s diagnostic busineses?

Policard: As you know Sanofi is a joint venture made up of 28% Pasteur and 72% Sanofi.

At Sanofi we have really three business; our business in blood viruses, our bacteriology or conventional microbiology business, and our automated immunoassay system, ACCESS® , which is focused on protein and allergy testing.

I'd say the approach for Sanofi is really a three prong strategy; establishing key collaborations, developing high technology niche markets, and dominating high growth regional markets.

To bring products to market we're not afraid of collaborations. We're collaborating with Johnson and Johnson with our HIV products in the U.S. and we're collaborating with Fuji Rebio in a joint venture in Japan. In order to deliver high value for our ACESS® we're going to need an alliance in the U.S.

Clearly we cannot go it alone if you look across our product lines our bacteriology business is not even represented in our U.S. or Japanese markets.

We envision ourselves as a leader in the development of disease state products and niche markets.

Sanofi's true strengths are in it's technology. We have an excellent technology source with Institute Pasteur and a broad patent portfolio in the HIV and probe testing area. We are a company that's very strong in pharmaceutical research and we can couple our advances and technology developments in diagnostics with drugs and this is what we plan to do, particularly in area of cardiovascular disease, aging, central nervous system disorders, and cancer.

As Sanofi there are five areas that we are most concerned about. That is Hepatitis C, cardiovascular disease, aging, diseases of the central nervous system, and cancer. In these areas we have the ability to couple our drug development with out development of diagnostic tests which can be used together to improve the management of the disease.

In these markets the value of the IVD product will be how well it contributes to the global control of the diseased state.

Patents will be much more important than they were in the 1980's. Patients will be the basis of licensing as companies strike more cooperative deals. I expect this will be a very significant issue in infectious disease HIV and the probe market.

And finally, we anticipate we will be one of the strongest companies in the developing markets and will get much of our growth from Asia, Eastern Europe, and South America.

Our direct marketing capabilities are the strongest in the emerging markets which now represent more than 25% of our business when they only represent 15% of the market. We are a strong player in markets such as Brazil, China, Eastern Europe and Asia. Here ,Sanofi as a company, has always been a pioneer. Sanofi was the first pharmaceutical company in Europe to go into China.

This is an area where I think, Sanofi has a significant advantage. In my opinion North American corporations know little about these markets. While it's true these markets today only represent 10-15% of the overall worldwide IVD market. I think it's reasonable that in ten years they will represent as much as a third of the worldwide market.

The growth that we have experienced has been in Brazil, Thailand, and Korea where we've seen growth rates of 15%, 13% and 15% respectively.

CaseBauer
Business Development and Research

Immunoassay Systems Usher in a New Order

CAP Today, December 1995, pp. 38

There was a time when laboratory Help Wanted ads specified the analyzer the medical technologist needed to be skilled at operating. But for more and more laboratory tests, push-button automation is becoming the norm. The new immunoassay systems are drastically reducing the labor required to conduct an expanding menu of tests, and they are hastening a perhaps equally significant trend toward workstation consolidation. Says Robert DeCresce, MD, director of laboratories at Rush Presbyterian - St. Luke's Medical Center in Chicago: "The same revolution that occurred in the 1980s in the chemistry lab with the introduction of the random access analyzer is happening in the 1990s with immunoassay."

A typical laboratory that purchases a random access immunoassay system may have multiple batch analyzers, some for routine testing and some for stats, and may send out certain tests to reference labs. By acquiring a new immunoassay analyzer, it can often phase out several instruments, free technologists so they can perform tests that were formerly sent out, reduce staffing, make a full test menu available at all times, and improve turnaround time.

In one hospital laboratory on Long Island, the numbers tell the story. Denise Uetwiller-Geiger, clinical chemist and administrative director of the laboratory at John T. Mather Memorial Hospital, conducted an integrated systems efficiency analysis to assess the impact of the lab's acquisition of a high-volume, continuous random access immunoassay analyzer.

We were looking for an analyzer with a broad test menu and one that would help us achieve workstation integration and eliminate manual stations which were labor-intensive, Uetwiller Geiger says. The new analyzer, with assay capabilities including therapeutic drug monitoring, metabolic, fertility, thyroid, and tumor markers, completed an average of 80 tests per hour, allowed workflow integration that eliminated extra analyzes, and made it possible for intensive manual stations to be eliminated. As a result, the laboratory projects annual savings of $18,892 on labor, about $10,000 in reagents, calibration, and controls, and $3,000 on parts - a total of $31,892.

"Reduction of analyzers decreases service costs, simplifies reagent purchasing, decreases quality control costs, and increases lab space," Uetwiller-Geiger said in reporting her findings at the Clinical Laboratory Management Association annual conference in August. "Random access improves efficiency, increases productivity, decreases turnaround time, and enhances service levels while reducing labor costs."

Personnel represents 60 to 80 percent of operating costs in the laboratory, where the need to contain costs is more urgent than ever. Thus, laboratories all over the country are replacing analyzers with new capital equipment that, because personnel expenses drop precipitously, brings savings right away. There is intense pressure on laboratories to reduce operating costs, says Robert Bauer, a consultant with CaseBauer & Associates in Dallas, Tex., "and a lot it directed toward the reduction of head count." But along with the pressure, Bauer adds, lab management has clout it didn't have before. As a result, more labs are overcoming the political and institutional constraints that may have prevented them from reorganizing or consolidating workstations in the past. More and more walls are being broken down between main labs and point-of-care and between subdepartments—but in his view the real driver is not simply the availability of instrumentation but the financial mandates of managed care's capitated contracts.

The primary thrust of instrument purchases right now, Bauer believes, is increased automation. "There is generally a continuum in the revolution that Bob DeCresce speaks of," he says, "when you look at the market as a whole. In the first phase, labs reduce costs—first by bringing tests internally that you're spending a lot of money for outside. In the second, labs take a manual or semiautomated state to a production state—in other words, front to back automation. In a third phase, labs reduce the number of automated platforms through consolidation." For better characterized technologies, like clinical chemistry, labs are farther along the continuum, he adds. In immunoassay they are just now reaching a phase 2 higher state of automation.

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With 25 manufacturers' systems competing, it is a buyer's market. Moreover, vendors have lowered barriers to acquiring new instruments by offering them through fairly aggressive rental programs. "With the higher cost per test for immunoassays, much higher than that of chemistry, reagent rental programs market instrument costs reasonably transparent to the purchaser," Bauer notes He compares the market to leasing programs for luxury cars: "Everyone can suddenly afford a BMW." In the lab, even though there is severe cost pressure, there is still much duplication of immunoassay systems.

In a sense, he says, the manufacturers are "flooding" the market because they are all jockeying for position. "What happens is you have multiple instruments in a facility and the manufacturers competing against each other for how heavily used they are. It puts labs in a good position." In fact, Bauer adds, "I don't know if labs have ever been in a position where they could leverage this level of automation."

He sees another effect of the kind of automation immunoassay systems are offering: progressive shifting of test location. First, reference labs are losing some business because fewer tests need to be referred. Second, as affiliated laboratory systems look across testing sites, they are setting up centralized testing locations and drawing additional tests from reference labs along with some low-medium volume tests currently dispersed across their network.

Aside from that, though, Bauer does not think managed care's greatest impact is getting labs to improve efficiency; rather, it is mediating the utilization of these tests. "Particularly for those with capitated contracts, they'll try to adjust utilization so physicians are using fewer tests. A good example is streamlined thyroid testing protocols. There is much more to be gained this way," he maintains.

In Uetwiller-Geiger's facility, which supports Long Island IVF and where fertility testing is 40 percent of the total test volume, one goal achieved by the new immunoassay analyzer was the creation of a central laboratory with an automated area and a non automated area. 'We wanted to have testing divided by technology," she says, rather than into traditional compartments such as hematology and chemistry. But in looking at analyzers on the market, she says, an important element in the selection process was the ability to go from radioisotopic testing to nonradioisotopic.

Many labs would like to get rid of radio immunoassay testing, agrees Mark S. Lifshitz, MD, director of clinical laboratories at New York University Medical Center. "I would, too." But there are some tests that can't be done using nonradioisotopic techniques, he notes. For example, the CA125 tumor marker test in the United States is still available only by RIA. His lab will have to decide eventually whether to continue doing a couple of RIA tests or to discontinue RIA testing and send the tests to a reference lab until they are available on automated immunoassay analyzers.

Dr. DeCresce points out that radioimmunoassay testing until about 10 years ago tended to be labor-intensive and was usually conducted in batches in separate areas, or in separate labs or often even nuclear medicine departments. 'If you ordered an RIA test in the morning, the run started at 10 and the sample got there at 11", it would have to wait. Because there were lots of standards and controls with RLA, he says, the laboratory might process a batch of tests only every other day.

When newer, nonradioisotopic systems came along, they were followed by stand-alone machines that were able to do tests automatically, more like a Xerox machine, he says. These automated batch analyzers worked most efficiently with batches but could also work for a small number of tests or single tests. Batches of varying size could be run frequently because there was much less overhead from calibrators and controls.

Because these small instruments were relatively inexpensive—though the reagents were not, they tended to proliferate, says Dr. DeCresce. "Someone would buy one analyzer for one test, and another for three other tests", he notes. "People had the luxury of finding instruments that did one or two tests well."

With the cost containment drive of the 1990s, however, labs have been motivated to take advantage of the new immunoassay systems that allow them to move almost all the tests done on dedicated systems to random access systems. "It's allowed us to revolutionize the way we run the lab," says Dr. DeCresce. By consolidating tests and machines, the lab can use one person for the work of three or four, obtain supplies from one vendor, and obtain far better pricing.

In most cases, laboratories buying the new instruments are nearing the end of their current analyzers' useful lives, so they are making capital outlays that would have been necessary anyway. But there are so many machines on the market now that an industry shakeout is inevitable, Dr. DeCresce believes, and the competitive advantage will go to the manufacturer that delivers more tests. "The real thing that drives the industry is the size of the menu," he said. "The bigger the menu, the more popular the machine, and menu is a function of the popularity of the machine," because the manufacturer can invest more in research and development.

Since his lab started acquiring new immunoassay technology, he says, "we've been able to move essentially all of our immunoassay testing into our chemistry lab with a couple of exceptions, and we've been able to consolidate virtually all our work onto two instruments." This has dramatically changed the physical space the laboratory occupies, too. He compares

the old setup to the days when televisions and videocassette players were separate, with wires and pipes all over the place. "Now it's cheaper to buy one unit together."

Some laboratories succeed in justifying the purchase of an immunoassay analyzer by marketing to physician offices, smaller hospitals, and corporations. At John T. Mather Memorial Hospital, improved turnaround is important to the patient population it serves. "As fertility specialists," says Uetwiller Geiger, "we are continuing to pick up testing from other specialists in the area and other assisted reproductive technology programs. They have very tight windows for turnaround times," she adds, since results of tests sent in the morning from up to 40 miles away may be used to adjust medication later in the afternoon. But not every lab can count on outreach, Bauer notes. "There's not enough outreach testing to go around," he points out.

An obvious implication for laboratory personnel is that there is much less talk today of personnel shortages. "In our hospital," says Dr. DeCresce, "it's meant clearly a drop in the number of people doing this work. Luckily, we've done it by and large by attrition. A number of people have been retrained and are doing other jobs." The impact on patient care, he adds, has been dramatically positive.

What about quality? The new immunoassay technology has raised concerns about the sensitivity and precision of the tests. "Every lab has to assess the performance characteristics and limitations of the analyzer to determine whether it meets the needs of the institution and the patient population," Uetwiller Geiger says. Dr. DeCresce views quality in terms of clinical utility. "In today's environment, these analyzers give us the opportunity to provide the full range of services with in the constraints imposed by lower reimbursement," he says. "To do that we have to make some compromises—not on quality when it affects patient care. But sometimes we spend a lot of extra money for very little benefit. That's why the pathologist has to make sure if they spend extra money they really get a benefit for the patient.

Down the road there will be even more consolidation, he predicts. Dr. Lifshitz cautions that labs need to be ready for dramatic budget measures. "Labs need to be proactive about understanding this environment and taking steps now to become as efficient as possible—before they're put in a position where it has to be done rapidly and with such drastic measures that the service level of the lab collapses."

Many laboratories are looking to change the way they work by using more technology. That should not mean leaping blindly into capital costs, Dr. Lifshitz says. "My feeling is that too many people have jumped into automation without asking what is our mission in the future." He stresses that all labs need to carefully consider issues of staffing, equipment, and test volume in asking themselves, "What can we gain from reengineering the lab another way?"

CASEBAUER
Business Development and Research

An Executive Interview with Donald Young, M.D., Ph.D., Vice Chairman of Laboratory Medicine, University of Pennsylvania

Diagnostic Insight, 1998 Interview

Donald Young, M.D., Ph.D., runs the clinical laboratories at the Hospital of the University of Pennsylvania as well as Presbyterian Medical Center. These hospitals are now part of the University of Pennsylvania Health System that owns four hospitals and about 100 physician practices; one of Young's jobs is to integrate the individual laboratory segments into a smooth-running, cost-efficient entity —while maintaining very high standards. "It's an interesting challenge and an opportunity to upgrade the quality of service," Young said. As part of this challenge, he is installing the same types of testing equipment throughout the system to ensure that all physicians obtain the same quality of lab work and that results are the same throughout the system. Besides the hospitals it owns, the health care system is also affiliated with several hospitals that refer their complicated patients to the "mother" facility. Young noted that since the development of the health system, "The kinds of patients we see now are different. The University hospital was once both a tertiary care center and a community hospital, but the community hospital aspect has almost disappeared. We recently did four transplants and one major trauma case in one night, and our busiest day ever was when we did five liver transplants," he said. "It's a change in the character of what we did in the past."

There has been some concern among the physicians in primary practice who are now part of the health system about the systemization of what they do and possible added paper work. "Even prior to the most recent round of ICD-9 code compliance regulations, the AMA has calculated that more than 40 percent of a physician's time was spent on paper work, and they fear that a health system may add to that," Young said. Young, who is Vice Chair for Laboratory Medicine in the department of Pathology and Laboratory Medicine of the University of Pennsylvania, Director of the hospital's William Pepper Laboratory, and Director of the Philip Custer Laboratory at Presbyterian Medical Center, has been with the University of Pennsylvania since 1984. Born in Belfast, at age five Young moved with his family to Scotland, where his father served as chair of pathology at the University of Aberdeen. He earned his medical degree from the University of Aberdeen and served as a lecturer in pharmacology there. He completed a Ph.D. in chemical pathology at Hammersmith Hospital and Royal Postgraduate Medical School in London. Young came to the National Institutes of Health (NIH) in Bethesda, MD, in 1964 as a visiting scientist, and became chief of the NIH ' s clinical chemistry service in 1965, where he remained until 1977 when he became chief of clinical chemistry at the Mayo Clinic. He was also AACC president in 1980 and IFCC president from 1985-1990. To unwind after 12-hour days, Young is writing a book about the effects of drugs on laboratory tests. He generally writes one book a year and has published more than 20 to date. He is married with three grown sons. In the following interview, Young discusses the workings and strategies of the University of Pennsylvania Health System.

Bauer: Philadelphia has two big health care systems: University of Pennsylvania Health System (UPHS) and Allegheny. The Hospital of the University of Pennsylvania (HUP), the lead hospital of UPHS, has been a very profitable institution for a number of years and at the same time Allegheny has been struggling. Why is this?

Young: Philadelphia has more competition between managed care companies than almost anywhere else in the country. Allegheny (of Pittsburgh) moved aggressively into the Philadelphia market in recent years by purchasing several hospitals and many physician practices. In my opinion, Allegheny overpaid for the hospitals that formed their net work and for their individual physician practices. As you might expect, their new net work was not well integrated or as well managed as some of the more established institutions in the city. So it suffered from the problems of higher operation costs. Allegheny was overextended in this market. [Note: Dr. Young pointed out that Allegheny was sold in November to Tenet Health Care; consequently, as a for-profit company, Tenet undoubtedly will change the way things are.

Bauer: Today, the number of beds in Philadelphia is roughly six per 1,000 population. By some estimates this is almost twice the number needed–a situation that occurs in other cities as well. How is the surplus created and how will these beds

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be rationalized?

Young: There are roughly 5,000 excess beds in this city. The intense competition for patients is driving reimbursement down, which in turn creates continuing pressures to reduce costs by treating patients as outpatients to minimize the number of admissions. As a result, we have a surplus of beds. As you might expect, no hospital is volunteering to close down beds. For now, it appears that beds will be closed only when there is a situation—such as has happened at Allegheny—that forces the closure of a hospital.

Bauer: So what is HUP's strategy in this market?

Young: We, too, are under pressure to contain costs as our reimbursement shifts toward more capitated contracts, and more and more of our patients are in managed care. Like Allegheny, our system is broad. The difference, however, is that we are much more integrated. First, while we, also, have purchased about 100 primary care practices, we were not under the general misconception that you make money with primary care practices. These practices are important because they get patients when they are sick, and our physicians can direct patients to our hospitals. In many respects primary care practices are loss leaders, but they feed patients into the hospitals. Second, we are building a truly integrated system. We are making the expertise of specialists in the medical center available to primary care physicians. We have a system-wide disease management program that specifies the precise management of patients with particular diseases. Everyone involved works together as part of a large team: physicians, laboratory people, dietitians, social workers. The goal is to treat our patients as well as they would be treated by a specialist in the medical center—and it looks as though it is beginning to work. We are already seeing the costs of certain diseases such as congestive heart failure reduced by 50%, and the number of people with unexpected ad missions to the hospital is dropping dramatically.

Bauer: Did this contribute to VPHS winning the National Health Care Quality award in 1998?

Young: The award, in large part, recognized our disease-management program, which is quite impressive. Typically, a disease-management plan is developed for a specific disease such as diabetes mellitus, focusing on reducing the major complications of the disease; in this case, kidney and vision problems. To do this, we need to make sure early on that patients are followed in a systematic way through the progression of the disease—that they see physicians in a proper time frame, that organ functions are monitored appropriately, and that progress is documented on a regular basis. As the condition worsens, it is addressed promptly—often in the field, which reduces the number of diabetes-associated hospital admissions. These care plans are like the critical pathways for inpatients. They cover everything from laboratory tests to drugs to procedures. We are trying to differentiate ourselves by showing that we are truly committed to the patient in the primary care setting.

Bauer: It seems that it would be easy to put acute care episodes into pathways rather than medical cases such as diabetes, which can span a life time. Are HUP's pathways capable of addressing long term windows and highly diverse patient events?

Young: You're right—we have been more successful with surgical cases than with medical cases, simply because surgical patients and trauma cases are relatively short-term events with a more predictable patient response. But our long-term goal is to describe the life of the chronic patient in the same way. The diabetic will have the disease for his or her life and our objective, of course, is to prevent the complications that normally end it early. It is true that this is complicated by the different stages of the disease, different ages of onset, and different lifestyles, but this can be characterized if you look at very large numbers of patients. Our plan allows us to collect uniform data on the diseases so that we can make adjustments to our practices. Initially, a team meets to develop the first pathway. There is a lead individual who coordinates key players who will be involved and oversees the pathway development. Then one individual is selected to be in charge of the overall program. He meets periodically with individual physicians in our network; his goal is to link those physicians in a continuing education process. Our primary care physicians are an integral part of our health management system.

Bauer: How is this program affecting the use of diagnostic tests?

Young: We have a fair number of research studies under way to determine what is happening. The change has not been as dramatic as you might expect. As these critical pathways are being implemented, the impact on the lab is really very little. We believe that more attention needs to be given to the use of lab tests. But I think one of the things to put into perspective is the contribution of lab costs to overall costs. We are completing an analysis of the costs of all DRGs in 1.3 million patients from 60 university hospitals. The average proportion of total patient costs attributable to the laboratory is about 6 percent for a surgical case and 9 percent for a medical case. Generally, laboratory costs are a small part of the total cost.

Bauer: In this environment, what is the strategy of the laboratory?

Young: The laboratory strategy mirrors the overall health system strategy. The University of Pennsylvania owns four hospitals and has affiliations with several others. The operating strategy is that HUP, as the major hospital, will provide support services to all patients in the other hospitals. By pooling resources, we help them treat their cancer patients better,

and they'll send us their complicated cancer patients. This plan of referring the most complicated cases to the lead hospital has brought the hospital up to 100 percent bed occupancy. And, hopefully, we are improving the quality of care in the other hospitals. As far as the lab is concerned, we want to transfer, where feasible, all routine (not STAT) tests to our lab and run them on the automated system we are currently installing; we hope to have it working by the end of the year. For the hospitals that we own, the-long term plan is that any tests requiring less than three hours turnaround time will be performed locally on site, and those with a same-day turn around time will be brought to our lab and put into our system. Additionally, we will support blood banks and STAT labs in the other hospitals. We expect our cost of providing tests to go down as the unit volume goes up. We anticipate that the send out work from our own hospitals and the affiliated hospitals will eventually come to us. Also, the physicians in our primary care network send their lab work to us. Basically, we are beginning to compete with large commercial laboratories.

Bauer: Are support systems in place or coming on-line that will support this effort?

Young: In the hospital, we have pneumatic tube systems and computer terminals in place on the nursing stations. With our new robotics system, test results will be ready in about 20 minutes from the time the specimen hits the track. When specimens come by pneumatic tube, results could be ready in as little as 30 minutes from draw time, instead of "by noon" like it is now. The goal is that when a physician anywhere in our system places an order, it is transmitted directly to our hospital information system terminal for processing. The nurse or physician will type in the patient's ID and indicate the lab tests to be done. These data go to the laboratory information system via the Hospital Information System that then sends the signal back to the nursing station and prints out a bar-coded label, which carries information about what tests need to be done on that particular specimen. The blood is drawn and the label is put on the tube. The bar-coded specimen reaches our laboratory by pneumatic tube and then literally all we have to do is take the tube out of the container from the pneumatic tube system and insert it onto the hematology or chemistry track. The chemistry track contains the automated centrifuge and can do all the aliquoting as well as create sub-tubes for all tests that are not performed directly on the track. For our primary care practices, test results will be printed on the printer in the physician's office. Because of the way the computer terminal functions, we also hope to reduce the number of errors. Screens are brought up that show the most common tests. When the nurse points and clicks different tests, those tests are ordered. And when we have built the entire disease critical pathway, we will be able to use the terminals to show the most appropriate tests for each patient based on his care pathway.

Bauer: If you are turning tests around in 30 minutes, will point-of care testing have a role at HUP?

Young: We are not wedded to the concept of a large robot, even though we think this is the way we would do it at the moment. In the future, if point of-care testing were to evolve and prices were to drop to a level competitive with those of the laboratory, I think we could support more point-of care-testing. We've set up a point-of-care testing committee that has the authority to say whether somebody may or may not conduct point-of-care testing and to decide what instrument will be used. The laboratory role is to provide quality assurance. The laboratory has a key role in this program. Decisions are made based on clinical need versus cost. In fact, we support our trauma program with point-of-care testing now even though it is more expensive. We believe that it is appropriate to do some testing in helicopters or immediately upon arrival of patients. It's not that point-of-care testing can't be done here, but the case of why it should be done must be presented to the point-of-care-testing committee. We permit some point of-care testing in the intensive care nursery. A key point is that everything will be done the same way so we can relate, for example, a prothrombin time in a physician's office to any other prothrombin time that was done in the health system. We perform a large number of bedside glucose tests all on the same device. We have also developed a protocol that indicates when it is appropriate to perform bed side glucose testing.

Bauer: What has been the committee's impact on bedside glucose testing?

Young: The number of tests is substantial, but less than it used to be. It was about 250,000 per year and we are now down to about 180,000 within the hospital. We feel that there is reason to reduce this number further, but this effort is rather low on our priority list now. We have many other higher priority "crises" to deal with in the hospital.

Bauer: Laboratories looking at robotics systems seem to be torn between buying a generic system or acquiring closed robotics from instrument manufacturers such as Abbott or Roche. How did you arrive at your decision?

Young: We felt it would be better for us to have a universal track that allows us to go to what ever manufacturer has the best analyzer so we are not locked out of a Bayer analyzer just because we have a Roche track. We can, hopefully, interface everyone's devices to our universal track.

Bauer: In closing, what major trends do you think are sustainable and will really play into the long-term development of the market–and which ones probably won't be with us long-term?

Young: It is going to be increasingly difficult with reductions in reimbursement to be able to deliver the level of service we would like and remain profit able. I think we are stuck with DRGs for a while. There are obviously a lot of concerns about DRGs, especially with how broadly they are defined. The DRG lumps together many people with different degrees of illness at different degrees of severity. A certain number of outliers has been excluded, but the normal DRG still covers many

different degrees of severity with the patient. I have a sense that Medicare and Medicaid will continue to focus on reducing the DRG payment. I think capitation payments will increasingly be challenged because there is a real concern among both patients and physicians that many shortcuts are taken that are not in the patient's interest. I think there are enough bad experiences that are beginning to get the attention of Congress. Outpatient fee-for-service payments are likely to be re placed by a form of DRG that I think will be more procedure- than disease-focused. An office visit would be a procedure. An EKG would be a procedure. But this change is going to be slow to evolve. I expected that it would already be in place by now, but it hasn't happened. We have invested much money and effort in developing a molecular pathology laboratory. These tests will have an increasingly important role in medical practice. We are very concerned about.

CaseBauer
Business Development and Research

Information Now Exists that can Redefine the Laboratory: But is the IVD Industry Ready?

Diagnostic Insight, Winter 1995/96, Vol. 16, No. 1, pp. 4

The lessons of laboratory information products have been "hard learned" by in vitro diagnostics manufacturers, said Robert Bauer, at the 13th Annual Symposium on Automated Information Management in the Clinical Laboratory, held at the University of Michigan Medical School. In the early 1980s, Bauer said, IVD manufacturers had "less than motivating" experiences when they developed their own mini-LIS systems and more recently as they tried to develop plug-and-play interfaces for third-party LIS systems. Bauer is a leading consultant to the IVD industry and managing director of Dallas-based CaseBauer & Associates. The symposium, directed by Bruce Friedman, MD of the University of Michigan Medical School, included a seminar sponsored by CAP Today examining the issue of instrument and LIS integration. As participants pointed out, laboratory informatics presents a special challenge to manufacturers in the in vitro diagnostics field. Symposium moderator and BMA President-elect Robert McGonnagle declared that "In our increasingly capitated, cost sensitive healthcare system, the care delivery enterprise wants to be able to view the laboratory as a black box. A 'virtual instrument,' one that can deliver timely and accurate results regardless of its internal processes and its configuration." The lab that proactively addresses the problem and meets the challenge, suggested McGonnagle and other speakers, will gain competitive ad vantage and enjoy significantly greater control over its own destiny.

IVD Manufacturers' contributions to informatics

"Many IVD manufacturers initially looked to data management and informatics products to provide a bridge during these longer product development cycles," Bauer said, "a glue-and-fix solution that manufacturers were willing to supply at very low prices, sometimes even at cost, to maintain customer favor and stretch out product life cycles while they developed their next generation product." The realities of clinical laboratory LIS needs were an early challenge that IVD manufacturers often failed to fully understand, Bauer said. First, the clinical laboratory market is highly fragmented, populated by thousands of unique operations, each with its own requirements. Second, since as much as 50 percent of a typical hospital's information transactions involve laboratory data, the information management task in the lab is not trivial, and IVD manufacturers often underestimated the scope and complexity of the LIS task. Third, the level of support clinical laboratories required was often beyond the scope of the glue-and-fix budgets of IVD manufacturers. In short, for the IVD manufacturer, the task far exceeded the benefit, according to Bauer, a fact that, for many, came to light only after the LIS products were developed and installed in laboratories. Bauer feels that another challenge for the IVD industry was LIS vendors' business imperatives. While the two industries share a common customer, IVD and LIS vendors operate from a different set of business priorities. To an IVD manufacturer, the LIS interface is not a revenue source, but a product feature that facilitates an instrument system placement. Instrument and reagent revenue is what drives the IVD industry. LIS vendors view this same interface differently. Post-installation consulting fees are important to many LIS businesses and can represent 40 percent or more of an LIS vendor's annual revenue, and the importance of these consulting fees is growing as the number of new system installations declines.

To move toward solutions, Dr. Friedman highlighted the need to get beyond our current dualistic, "us and them" models and seek "co-opetition," that is, solutions that bring a Hitachi, Abbott, or Beckman to the table with a Cerner, Sunquest, or CHC. Clearly, "there's all kinds of interaction going on between these two camps now," he pointed out. One way to frame the opportunity, Dr. Friedman suggested, is to think in terms of dynamically linked "up stream" and "downstream" integration of data. "Up stream" integration, which includes, but is not limited to, IVD-LIS interfaces, has a better chance of happening if the two parties can establish a common agenda. Success upstream will, in turn, facilitate the downstream process of delivering value to physicians, patients, and the entire healthcare enterprise.

Reducing information float

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Dr. Friedman believes that there are opportunities in data handling to reduce information "float" in the lab. Drawing on the analogy of travelers' checks, which are paid for at purchase and redeemed later, being, in effect, a loan, Dr. Friedman defined the laboratory information float as the time period beginning when a clinician orders a test and ending when the clinician "knows" the result. In an age of time-based competition; laboratory competitiveness and success will increasingly derive from the ability to reduce information float. What we are seeing in our deployment of sophisticated work stations, automation of front end processes, innovation of POC testing, and refinement of the LIS with rules, reflex testing, long-term archiving, and clinically specific reporting, as well as streamlined IVD-LIS interfaces, is nothing more than better ways to do just that.

Lack of standardization and cooperation as impediments to progress

Calling the separate evolution of instruments and the LIS "interesting and sad," the Cleveland Clinic Foundation's Dr. David Chou went on to outline the progress that has been made in interface technology. Not much more than a decade ago, Dr. Chou pointed out, it was not uncommon for a laboratory to buy a major analyzer only to find it had no LIS interface capabilities at all. When minicomputers first began to appear in the lab, in the 1960s and early 1970s, the typical analyzer's "interface" capabilities were merely an extension of the ability to print hardcopy chart records. Only in the late 1970s did interfaces based on the soon-to-be ubiquitous RS232 emerge, and even then labs typically had to pay extra for them. However widespread it may have become, the RS232 interface is rapidly becoming obsolete, Dr. Chou said. Its electrical and connector specifications are limited. The maximum data-transmission rates are too slow. The requirement that instruments can be no more than 50 feet from the computer is almost laughable in an environment where a data center may be miles from the laboratory. By the 1980s, newer, unidirectional and bidirectional interface technology had emerged, and by the late 1980s barcode technology was also playing a growing role in the lab and thus in the interface picture. In the 1990s, Dr. Chou said, we have entered an era of standards advancement and promulgation, most notably under the aegis of the American Society of Testing and Materials. While we are not likely to see true "plug and play" interfaces soon, we are making progress toward a more comprehensive, stream lined instrument-LIS interface environment. Remaining barriers pertain to the inherently slow nature of standards development, depending as the process does on volunteer expertise and lacking as it does the involvement of a clearly dominant vendor - the clinical laboratory equivalent of a Microsoft or an Intel who can drive the process by sheer weight of influence and vested interest. Also, there does not yet exist independent means to verify interface protocols, Dr. Chou added. Standards do not adequately address the special demands of high volume analyzers. Delays are inherent in system design and FDA approval. For all its potential benefits, point-of-care technology has "set back interface technology 10 years," Dr. Chou said, since few if any POC devices fully support data transmission to the LIS.

IVD Manufacturer becoming better equipped to expand their role in informatics

Robert Bauer also observed that IVD interest in laboratory information management is on the rebound, driven by the manufacturers' desire for more product differentiation in a market where product offerings are increasingly reaching parity. One result is the wave of new workstation management systems from Abbott, Johnson & Johnson, Beckman, and others, which are filling voids that LIS systems and vendors have not been able to address rapidly, namely, lowering the cost of interfaces, providing modern information management tools such as e-mail to older LIS systems, and optimizing the workflow across two or more related instrument systems. Will the IVD role in lab information systems become more significant? Yes, Bauer predicted. All indications point in this direction. First, unlike the LIS, which made more sense to develop on a laboratory-wide basis, combination LAS/LIS solutions are likely to develop and be more affordable on a workstation basis rather than across the en tire laboratory. Second, IVD manufacturers are continually broadening the definition and scope of their core products to establish competitive advantage. Front-end automation is a developing trend. Third, the consolidation of IVD manufacturers begets larger organizations with a broader breadth of instrumentation that can be integrated with out the complexities of multi company coordination.

The impact of laboratory automation on laboratory information management

Possibly half of all clinical labs will embark on automation projects within the next five years, predicted Dr. Rodney Markin. In the process, this change will radically alter our current paradigm of information development and management in the lab. Dr. Markin is professor of pathology and microbiology, Departments of Pathology and Microbiology, at the University of Nebraska Medi cal Center. In Dr. Markin's view, arriving at that new paradigm will require improving our under standing of what happens in the laboratory. That in turn will mean reevaluating laboratory processes from several perspectives and on several levels, from local work-bench to very large, multiorganizational healthcare information net work. What we will find in this process may surprise us, Dr. Markin suggests. Most labs, he believes, do not fully understand the extent to which specimen flow differs from information development and management. Automating and integrating them will, among other things, force us away from our current view of the laboratory as being composed of many smaller, relatively independent sub sections. As a result of this change, we will increasingly find our selves thinking in terms of an LAS–a laboratory automation system–as well as an LIS, Dr. Markin declared. Moreover, that LAS will be come not just an important element in effective laboratory design but its essential starting point. "Ideally, if we were going to step back, look at the processes in a laboratory, and design a lab information system from scratch," Dr. Markin observed, "we would start with LAS and then move on to instrument interfaces and the LIS."

Does the industry have the motive, means, and opportunity?

Given that the clinical laboratory is becoming more physically dispersed, no longer contained within four walls or the "lab-as-factory assembly-line" model, the concept of a "virtual lab" has become more relevant, Bauer added. "With developments like point-of-care testing, with nurses running tests, the lab is becoming harder to define in a physical and organizational sense," he said. But, according to Friedman, making the virtual lab a working reality will require further evolution of interface protocols and standards, a better understanding of the complex interdependencies among specimen movement, information management, and workflow, and a much clearer grasp of the process control issues that the introduction of robotics and front-end automation is now raising. It will also require new initiatives, new business and technology arrangements between two industries accustomed to operating at an arm's length from one another, speakers agreed. "Aligning all these competitive objectives is not unlike asking Federal Express in the 1970's to invent the fax machine," states Bauer, "the virtual laboratory is going to happen... its just not clear yet who is going to lead the process."

CASEBAUER
Business Development and Research

An Executive Interview with Michael J. Quinn, President of Fisher Scientific Company

Diagnostic Insight, 1996 Interview

Michael J. Quinn grew up in Troy, New York, the oldest of five children in an Irish Catholic family. "I was an inner-city kid —I learned to work when I was eight years old. I knew what it was like to get my hands dirty and stand on my own two feet. I feel very fortunate to have an education, but my real education was on the street." His father was a machinist who, with no college education, rose through the ranks to upper-middle management. "I saw him struggle, and I admired him," Quinn said. Married for 26 years, Quinn has 22- and 17-year-old daughters. To relax from 80-hour work weeks and a hectic travel schedule, he golfs and plays in an amateur softball league. At 52, Quinn has spent much of his career in the distribution environment. Recruited from the University of Buffalo in 1967, he began working at Scientific Products as a sales trainee after graduation. He earned rapid promotions to become SP's first Vice President of National Accounts in 1974, then Vice President of both Marketing and Sales. He became General Manager of V. Mueller, AHSC's operating room division, and in 1978 returned to SP as President of its industrial division —running a multi-million-dollar company at age 33. In 1983, Picker recruited him; after a stint as Executive Vice President at Bergen Brunswig, he became Fisher President a year ago. He has relished coming full circle. "One of the reasons I came back to this industry is that I enjoyed my job at SP and being in laboratory distribution more than anything else I've ever done. It is phenomenal that I had a chance to come back to the industry —to a company that I competed with for 15 years —and end my career the same way I started it. I'm very proud to be associated with this company." Another source of pride for Quinn is his "Fisher University". Through an affiliation with Pittsburgh universities, professors help train Fisher people in intensive managerial programs. "We've trained our managers in hiring, counseling, compensation —people and customer skills, finance, marketing. For practical topics such as sales, we bring in people who've walked the mile. It's a unique concept. We're a prime example of what should be going on in American industry—the evolution of business into education," he said. Quinn's approach to managing Fisher is "always, first and foremost, results —the importance of providing shareholders with value. I've brought many excellent managers to Fisher with me. I have wonderful, extremely competent people, and we share a similar philosophy." He credits that philosophy—customer focus —to former SP chairman Karl Bays, "one of the best health care executives in America. He always focused on the importance of the customer, and I have never forgotten that." In this interview, Quinn discusses developments within both the industry and Fisher.

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Bauer: What role will distributors play in a tougher managed care environment?

Quinn: There are very interesting trends developing in health care, with rapidly evolving integrated health care net works. Acute care institutions, nursing homes, physicians' practices, and pharmacies will unite locally, and you'll see health care management and delivery systems as focal points in metropolitan areas such as Chicago, New York, and Philadelphia. Distributors will become logistics partners to customers who are uniting under the umbrella of health care net works: Customers will need someone with logistics and systems expertise to act as 'captain of the huddle' to deliver products within the net works —when and at the price they need them. To do this, distributors will need to form alliances —laboratory, dietary, med/surg, pharmacy —similar to how the integrated net works are aligning varied medical services. Very few distribution companies are recognizing the importance of doing this —they're still all trying to do it on their own, and I don't think that's going to work.

Bauer: Laboratory distributors appear to be stepping back from backward integration into high-tech products, with ventures such as Instrumentation Laboratory/Fisher and MicroScan/Baxter being abandoned. Central purchasing and distribution has not been a primary basis of competition for capital and high technology laboratory products. What happens in your integrated network scenario?

Quinn: Scientific Products tried for years to be a major player with the higher-volume, higher priced capital equipment; I don't think that's distribution's core competency. Once you hit the upper middle level of capital equipment, you need specialists who concentrate 100% of their time selling, servicing, and understanding it financially. We're not built for that — we're logistics experts. We can take the juice that comes from those products and handle that competently, making sure

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people get what they want when they want it —and are serviced properly. Reagents could come through a distributor, or the manufacturer could be part of the alliance. If I want to differentiate my portfolio of products and services, I may want to have an alliance with a Johnson & Johnson or an Abbott, which could really gain from our systems technology. We'd make sure that their customers have the highest service level plus accurate accountability: who, what, when, where, and how. Some distributors are carrying huge inventories on small margins. I think we'll have to be much better working-asset managers; that means taking a look at the manufacturers we're carrying in various categories . Fisher is going to represent the best manufacturers in the industry, the customers' choices of manufacturers, but we're probably not going to continue to be all things to all people and I believe every one of my competitors will do the same thing.

Bauer: So you'll be brand neutral, letting customers, as a whole, select the brand they prefer?

Quinn: Yes. But I won't be able to have every customer tell me what he or she wants because that's how I found myself where I am right now —carrying, for instance, 11 manufacturers in a category when I should have only three. I'll have to take the biggest customers with the biggest collective bargaining capability. That's where the formulary comes in: You'll see big groups begin to pare their product offerings to their own institutions. Some of the larger groups are talking about keeping sales people out of their institutions. If they had a logistics partner, the sales people would have to go in front of a review committee; if your product is accepted for the formulary, you're in, and if it isn't, you're out. Right now if you're out you're never really out because you can call on the hospital or sell around the corners —but those days are almost over. A lot of manufacturers —especially those in pharmaceuticals —are threatened tremendously by this.

Bauer: Customers are looking for more services and better price on distributors' already small margins. What will happen to price?

Quinn: In consolidation you have a marketplace that's demanding lower prices, and market producers claiming they're not making enough money. With consolidation, the water level stabilizes, and I see that happening in many industries such as pharmaceuticals, where pricing is leveling off. People realize that if you want quality products and services you're going to have to pay a fair price for companies to deliver that. I think we're getting to the end of the price game. The price/value relationship is way out of whack in our industry. We're in a very high tech industry that requires a tremendous amount of R&D and engineering time as well as capital investment, and when you look at the gross margins some of these products are carrying, it's unfair to the producers. Across the board manufacturers and distributors are basically saying, 'I'm not going to take it any more. ' They want to improve the price/value relationship.

Bauer: This is a transitional period in laboratory products and distribution. After exiting the clinical laboratory distribution market with the sale of Instrumentation Laboratory, why is Fisher re-entering this field now?

Quinn: If things had been in reverse sequence [purchasing CMS before Instrumentation Lab], we would probably still have IL, and it would make better sense because we now have the channel to the customer. When Fisher bought IL, it took industrial research people and tried to make them clinical —that's very difficult. When you have a clinical company such as CMS, and have the manufacturing vertically integrated, it's much easier to accomplish. You'll see additional acquisitions that will strengthen and broaden our portfolio. When our people see a customer, they'll be on equal or better footing than anybody they compete with.

Bauer: What is Fisher's vision for growth and success, and how does the CMS acquisition fit into Fisher's overall strategic direction?

Quinn: If you look at the sequence of events when Baxter basically sold off its industrial research division to VWR, and a few months later Fisher bought CMS, Fisher became the widest channel of distribution for clinical and scientific products in the entire industry —worldwide. As a result, we have been approached by manufacturers that I never would have bet on knocking on our door, asking us if we'd be interested in representing some or all of their products. It gives me a wider opportunity to choose high-quality products. Fisher has the capability to raise capital to do the right things right at CMS. I think you'll see us expand its market basket. We'll give CMS a real shot in the arm from a systems standpoint, including SupplyLink [see below]. Our logistics capabilities certainly will complement CMS products tremendously. We intend to take very good companies and make them better —and very quickly.

Bauer: How will Fisher's ownership improve CMS's position with corporate buyers and suppliers, within the growing demands of the managed care environment?

Quinn: Fisher developed a system called SupplyLink for our research business that many CMS people and their customers —the larger groups that have seen our systems technology —are asking us to bring into the clinical/hospital side of the business as a leadership vehicle. When I was at Bergen, I thought they were a leader, if not the leader, in systems development on the hospital/medical side of the business, and I believe now that SupplyLink is at least two years ahead of any thing I saw there. SupplyLink is an electronic mall that allows the establishment of formularies in all major categories of procurement—pharmaceutical, dietary, med/surg, and laboratory—right down the line. Each formulary could be different: Once established, it is exclusive to your hospital, your clinic, your nursing home—and it allows you to access it as your catalog. You can then regulate usage by the people who work for you who currently go outside the system and buy outside

of contract. For example, if a group has proprietary agreements with a number of companies, and our collective bargaining power and pricing are based upon giving them all of our purchases for their pricing, today maybe 70% of the people go along with the contract and the rest do what they feel like doing. SupplyLink circumvents that because every time somebody pops outside the formulary, it tells you what hour he did it, his department, his name, what he bought and at what price he bought it —and the variance between what he bought and what he was supposed to buy . It changes a very liberal system that doesn't have optimum controls for properly managing healthcare expenditures into a very, very disciplined, exacting system that allows you to keep track of every penny 24 hours a day, seven days a week.

Bauer: Fisher has been expanding around the world. CMS is primarily a U.S. organization. How does this fit with your globalization strategy?

Quinn: We are setting up our organization around the world to be multi-faceted. Our Canadian operation is a perfect example: It's both clinical and industrial, and it does very, very well. We're the number-one company in Canada in terms of market share. It's one of our better performing divisions, and is really a model for the way we'd like to be in other countries. We're beginning to integrate internationally by taking some Fisher and CMS people who have core competencies needed in Europe and the Asian Rim to help bring the Fisher philosophy to those countries. Fisher's international focus is well managed and working effectively.

Bauer: What are the challenges of your integration? How will you handle the integration of facilities, services, systems, and sales organizations?

Quinn: I've integrated companies before, and I've done it both the right way and the wrong way. We decided we weren't going to take our day-to-day key managers and have them try to do their jobs every day and also try to fit in integration. We hired an integration manager with a dedicated team of professionals in all functional areas; their only job is to integrate these two companies. It's working very smoothly and very quickly. We're not in a race with VWR or Baxter; we have our own defined time limits and cost reductions that we want to accomplish to make ourselves stronger in the eyes of the financial community and our share holders, and I'd say we're ahead of schedule. Fisher is totally dedicated to being the best company in our industry worldwide—rated as such by our customers.

CASEBAUER
Business Development and Research

An Executive Interview with Alan Nelson, Ph.D., President and CEO of NeoPath Inc.

Diagnostic Insight, 1996 Interview

Alan Nelson, Ph.D., planned to be a rock and roll star when he was growing up outside Phoenix. Following his parents' divorce, Nelson became "pretty individualistic," playing in a rock band and reading a great deal. Because "one of my nightmares was that I'd end up in a dusty little town in Arizona for the rest of my life," he sold his drums to help pay tuition, and headed to southern California. At USC, Nelson earned a B.S. in physics, which led him to work at NASA's jet propulsion laboratory. "That," he said, "is where my interest in imaging started." At NASA, Nelson helped design an imaging spectrometer for Jupiter satellite Pioneer 10. He then joined Xerox's Medical Diagnostics Division (now defunct) as lead engineer on a mammography system, his first experience working in cancer prevention. Nelson left Xerox to pursue a graduate degree at the University of California at Berkeley, and earned a Ph.D. in biophysics, specializing in medical imaging. Based on his engineering, science, and medical background, Nelson was appointed jointly to the Harvard and MIT faculties, and he held an endowed chair at MIT. He created a Radiological Sciences program for MIT and Harvard; it was the country's first to offer Ph.D.s in imaging and other aspects of radiology, as well as MD/Ph.D.s. On sabbatical in Europe, he was named visiting scholar to the Royal Society, and worked to break through departmental barriers in Europe's academic system, to effect collaboration among radiologists, pathologists, electrical engineers, physicists, and computer scientists. Recruited in 1987 by the University of Washington, Nelson constructed and chaired the Center for Imaging Systems Optimization, for which he gained funding from companies such as IBM, GE, and Siemens. There, he developed a Ph.D. program that ultimately competed with the one he'd built at MIT/Harvard. Nelson joined forces with venture capitalists in 1988; together they founded NeoPath in January 1989 in Redmond, WA. Nelson later resigned from UW to run NeoPath. University colleagues questioned why he would give up his tenured position to head a company that might fail. "Taking a risk meant that, if I was successful, I could help save some lives —and that was important to me," Nelson explained. "I never had a sense of entitlement -- I always thought that you had to continually earn your own way and find a way to contribute," he said. When not at NeoPath, Nelson, along with his wife Sharon Everson, likes to restore old houses; they've lived in seven different homes in the last 12 years —from Victorians to barns. Nelson learned to install plumbing and electricity and to refinish floors. His parents, who were both farmers at one time, taught him much about hard work.

In the following interview, Nelson, 47, discusses his work at NeoPath: developing the AutoPapR system, a fully automated instrument approved by the FDA to rescreen normal Pap smears to find abnormal cells that humans may have missed.

Bauer: How has the diagnostics industry changed in the last five years, and how has this change affected start-up companies?

Nelson: One change is a tremendous focus on the economies surrounding the diagnostics business. The financial picture for the clinical lab business, particularly in the last few months, is almost a disaster. The largest laboratories have huge pressure to improve profitability —both gross revenues and cost containment. Organizations like Laboratory Corporation of America, the largest clinical laboratory in the world, are struggling from the merging of two cultures —Roche Biomedical and National Health. Their stock has hit an all-time low.

Corning, another of the laboratory giants, is now being spun off as an independent company. SmithKline, which I believe is the healthiest of them all -- is probably looking at further consolidation, driven principally by economics. It's becoming more difficult for a clinical laboratory to operate in this environment; by the end of this decade there will be a handful of centers of excellence that have figured out how to conduct business in this environment —and they will dominate the market. In terms of start-ups, NASDAQ issues recently took a beating, and a lot of IPOs were pulled off the market. I believe that many pending IPOs did not deserve to be public companies. There's a very high possibility that a lot of those IPOs, had they been successful, would have left shareholders very disappointed. All in all, even though it hurts, the shakeup in the IPO industry has probably been a good thing.

Bauer: What are the most critical challenges facing start-up companies today?

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Nelson: Sourcing cash for the business. There are fewer and fewer investment firms willing to invest in seed capital for the earliest stages of a startup. Fortunately, they are still willing to make smaller investments to nurture companies. We're going to need more sustaining capital in the pre-IPO stage to support companies, because I think IPOs are going to be further down the road. Before they have a successful IPO, companies will have to be more mature and less of an investment risk. To start a company, you might have to consider financing it yourself to get it underway, then raise capital. Previously, capital was available to organizations that had a compelling vision but hadn't demonstrated any value -- I think those days are gone.

Bauer: As you've noted, some companies have had very difficult IPOs; some have been pulled back. But Wall Street was good to you in your $62 mil lion effort and also to Cytyc, in its $44 million effort. What was the attraction?

Nelson: For NeoPath the attraction is that Pap smear screening is viewed as a potential breakaway market. A successful company could be come a billion-dollar enterprise. That's exciting to Wall Street, as is the possibility of revolutionizing an industry that today is conducted very much the way it was 40 years ago. NeoPath has continuously delivered on milestones —we lay them out years in advance and hit them on target or exceed expectations. Investors can look at what we've promised and see that we did it. We've been successful with the FDA process, which impresses investors who would have expected that we ' d still be waiting for FDA approval on our first product. Our clinical studies were very thorough and convincing, and we got PMA approval from the FDA in only seven months —the fastest ever for a Class III medical device.

Cytyc also now has a favor able track record with the FDA, and they do have a very nice technology. I think they're viewed as a complement to NeoPath: Cytyc builds a better Pap smear, and NeoPath provides a more accurate and economical analysis of the smear.

Bauer: Your recent FDA approval for AutoPap for rescreening normal Pap smears was a landmark in this field. How did it come about?

Nelson: In the late 1980s, there was a very insightful article in The Wall Street Journal that identified shortcomings in Pap testing. The problem is that the Pap test is very difficult. The cervix is scraped, cells are spread onto a slide and it is sent to a clinical laboratory; it's stained, then viewed by a cytotechnologist with a college degree and one year of specialized training. The cytotech looks for very subtle changes—early indications of cancer—in many different kinds of cells. The cytotechs do find most of the disease cases and identify most women at risk of getting cancer, but they also make mistakes—which can become tragic mistakes. They occasionally miss a cancer (false negative) —the patient is told she's normal and the next thing she knows her life is threatened. This is a particularly difficult industry because a Pap smear's cost is already at rock bottom. At a few dollars, it's the cheapest cancer prescreening test available in the clinical lab business—it's very undervalued. It is one of the few tests that has been successful in the prevention of any cancers. In the U.S. it has resulted in a 70 percent reduction in death rate just by early detection. But for a product to be successful in this business, it has to improve the standard of care and curb cost.

Bauer: In the case of rescreening negatives, aren't you adding cost to the test procedure?

Nelson: Yes —we're trying to minimize that but there's almost a law that if you want more quality, you have to pay more. There are many ways to get quality. One that requires no technology is simply to rescreen the Pap smear. That will definitely raise the quality but will double your cost. Our instrument is not as expensive as rescreening -- we come in at about half that cost. We charge customers $3 to $4 for the QC of their normal slides. It feels like a cost increase but laboratories look at it two different ways: One is incremental cost—over and above their conventional rescreening. The second is value: AutoPap detects many cases they've missed —which for big laboratories creates unfavorable exposure. Some of our largest customers took the amount of their settlement costs for a year for misread Pap smears, divided that by the number of Pap smears, and came up with a figure between $1 and $3 that they pay in litigation. When we charge $4 to $5 and recover most of their serious misses, they're willing to give us their $1 to $3 —something that will pay for itself in the long run. So it feels to them like a $1 to $2 increase for quality, which most of the clinical laboratories are willing to embrace because they want to deliver the highest possible quality. And in an integrated health care system that insures patient lives, this $1 to $2 increase can easily be recovered in downstream medical costs.

Bauer: Is there a cost savings to the laboratory to use AutoPap as the primary screener?

Nelson: Yes. That's what makes this all work. The principal cost in Pap smear screening is labor, so if our machine can call a test normal, and the cytotechnologist doesn't have to review it, the lab will save about $5 to $6 for that Pap smear, minus our charge. Our application for primary screening is now before the FDA; it shows very compelling clinical evidence that we can remove up to 30 percent of the workload and also offer a much higher quality standard to the lab. Removing up to 30 percent of the workload, averaged over all slides, saves the lab roughly $2 on each slide —and if, using our QC system, they're al ready paying a dollar or two more, it's either a break even or a cost savings of perhaps 50 cents. Primary screening would allow the lab to reduce its cost per slide or grow its business or both, and still retain the quality of the rescreening capability to detect human mistakes. We think we have the only solution to both of those issues: cost containment and increased accuracy. Right behind the primary screener we plan studies to increase the sort rate, so our

objective is to continue to provide software upgrades on the system and to further reduce its costs.

Editor's note: The FDA Hematology and Pathology Devices Panel recommended not to approve the AutoPap system as a primary screener at this time. The advisory panel asked NeoPath to present additional, on-site data that use of AutoPap as a primary screener of microscopic images from Pap smear slides is superior to the current standard of review —by a cytotechnologist followed by quality control review. Nelson said that NeoPath will "work vigilantly to answer all of the panel's questions and resubmit this matter to the FDA's Division of Clinical Laboratory Devices. "

Bauer: There's been concern about taking the cytotech out of the process and having a "black box" What must happen to change that in practice?

Nelson: Actually, I don't think a lot has to be done. At first, we thought that if we developed a black box it might create some discomfort in an industry where people are used to looking at things, but we have not found that to be a significant issue. In fact, we were at an analyst panel recently in New York that included Dr. Wilbur, a very well-known cytopathologist at the University of Rochester, and he was asked point blank: 'The AutoPap is a black box that doesn't show you pictures; does that bother you?' He said, 'Why should it? If the clinical data are good science and show strong evidence that I don't have to look at pictures, then I don't want to look at pictures.' He used as his analogy the complete revolution that took place in bloods, when Technicon, more than 15 years ago, introduced a black box to analyze blood. At that time, bloods were all done manually by a hematech looking under a microscope; that doesn't happen today. All bloods are analyzed on instruments that provide analytical data, and no human looks at a blood sample. I believe that the same thing will happen to Pap smear screening and other related specimens. Technology will provide higher accuracy, a better cost basis, with total automation. NeoPath remains unique in the industry —we made the decision to completely automate this business and therefore we did not make the cytotech a necessary part of the system. There are no pictures to be viewed—the instrument really is a black box that doesn't depend on a human. We do, however, have the capability of showing pictures, and we use it internally to train on.

Bauer: As you look back on this technology's development, what lessons did you learn?

Nelson: A Pap smear has hundreds of thousands of cells on it, and we reasoned —and pretty well proved —that we could generate statistics that would let us analyze a subsample of that specimen and get the right answer. But when we talked to doctors, they said, 'Wait a second —you're not going to look at all of the Pap smear?' That's what sampling means —we'd be looking at enough to get the correct answer. But the doctors needed assurance that we'd look at the whole Pap smear, because they're haunted by cases where there may be only one or two abnormal cells; if the lab misses them, and the instrument only samples, it may miss them as well. That was a wake-up call, which fortunately we got before we'd invested heavily in a sampling scheme. That instantly raised a technical barrier, and increased our investment: There are four gigabytes of data on one complete Pap smear under high magnification, compared with a mammogram, which has 1/500th of that data. We had to develop technologies including a unique computer —it's patented and we own the chip design —specialized to handle massive morphology computations.

Bauer: How critical are third-party payers to the success of your first-phase product?

Nelson: They haven't been critical—all of our customers have made the decision to go for ward with quality control even though third-party payers are not necessarily covering it. I think they realize it is better medicine and in the end will be better business, so they're willing to bite the bullet. At the same time, they've used this as an argument for third party payers: The industry has changed —this really is a much better test and it is our best opportunity to get a fair reimbursement. There comes a point where if reimbursement is too low it will stop women from getting a vital test. Some of those arguments fall on deaf ears, while other organizations are finding some success.

Bauer: What tenets have guided your approach to managing NeoPath's employees?

Nelson: I'm a very fair person. I'm a strong leader, but I define leadership as perhaps the most democratic process there is —you're only a leader because people want to be led by you. That's my philosophy and I let everybody know it, and therefore I have to earn my leadership every day. I strive to inspire people to exceed their personal expectations. I did that as a professor and I do it at NeoPath. One of the greatest inspirations for people is to know at the end of the day that they've done something even they didn't think they could do. It's created an amazing sense of vitality. At NeoPath, we have the largest assemblage of world experts in the industry. We get the best, and we make no compromises. If we have the best team in the world we have the best advantage, and we'll create the best technology and the best product.

Bauer: What does the future hold for NeoPath?

Nelson: We intend to do many things besides Pap smears in the future: sputums, for early detection of lung cancer, and probe analysis . There's a wonderful opportunity to combine with a strategic partner -- a biotech firm making gene or antibody probes —so that we can provide accurate and inexpensive analysis of those probes. We're also looking at histology, determining whether a surgical biopsy is cancerous. We'll start investing in a development program next year, which could result in a product on the market in a few years.

CASEBAUER
Business Development and Research

Recasting IVD Strategies For Tomorrow's Markets

Messenger, Fall 1994, Vol. 21, No. 3, pp. 4

As managed care networks and health maintenance organizations (HMOs) consume a growing percentage of the hospitals and physicians' practices in the United States, the clinical laboratories are losing their autonomy as well. The trend toward centralized management of diagnostic functions for networks or HMOs offers opportunities for sales on a much bigger scale than in the past, but also dictates changes in the way in vitro diagnostics (IVD) manufacturers to business. To reach this "new" customer, these manufacturers must focus on developing different types of products, become sensitive to different forces driving the market, and radically revamp their approach to distribution and sales.

Until recently, each clinical laboratory functioned autonomously, as an overly customized collection of workstations with idiosyncratic methodologies and capabilities. Labor and facilities account for fully two thirds of diagnostic testing costs. Managed care organizations, looking for ways to cut costs, see the opportunity for economies of scale by integrating independent laboratories under the authority of one central decision maker. The laboratory director for a network or HMO may, for instance, be responsible for the diagnostic functions of 5 hospitals, 15 clinics, 2 ambulatory care centers, some day surgery centers, a home health nursing organization, and 20 group practices.

This central figure may have the same level of education and in fact may have previously directed an independent laboratory, but now his or her perspective and objectives are quite different. He or she must strive for optimal use of 60 or 100 work stations rather than 12 or 20.

Reengineering each testing site to function as part of an integrated whole is a daunting task that includes updating and networking information systems, standardizing billing practices, planning transportation of specimens, and optimizing use of equipment and personnel. The thousands of transitions across the country are not likely to be orderly or even readily apparent to the casual observer, but they have far-reaching implications for the IVD manufacturer.

ECONOMIES OF SCALE

To meet the needs of this buyer, manufacturers of diagnostic equipment will have to give up their myopic focus on automation, menu consolidation, and capital equipment repackaging. Racing to eke out incremental improvements in a crowded instrumentation market, diagnostics companies are investing in research and development at rates greater than 10% of sales. As instruments become more complex and expensive, reagent rental programs are harder pressed to recover the equipment cost.

The central laboratory director will not need complex, expensive machines that can each run 100 different types of tests. With centralized management, each instrument can be dedicated and operate at high volume. The new laboratory director may, for instance, choose to dedicate a system at only one site to running all radioimmunoassays for the network, knowing that results of such tests are not typically expected within less than 48 hours.

Standardization is key to optimizing the networked laboratory without walls. All sites will ideally use the same model of chemistry analyzer, so that normal ranges will be consistent. Data terminals installed on every floor, in every emergency center, and in every physician's office will capture test results so that they are available to whoever next treats the patient.

To ensure capture of data, the director might specify that all home health nurses bring patients' blood samples to the laboratory for analysis instead of using handheld analyzers. Since bedside blood glucose testing requires stringent quality control, training, and monitoring, the laboratory director may dictate that one type of handheld monitor be used at all sites within the network. Such a move allows institutionalization of a training program and, of course, negotiation of a rock-bottom

price for the monitors and supplies.

Clinical Laboratory News

WHEN IS FASTER NOT BETTER?

Americans love speed. Our fascination with turnaround time is unequaled in any other world market. While STATs are clearly needed in the emergency room and intensive care unit, the value of speed in the outpatient setting is harder to establish.

Historically, diagnostics manufacturers have striven to reengineer tests to allow point of care testing (POCT), regardless of whether the immediacy of results confers any added benefit. In the managed care setting, price performance and outcomes research are the new buzzwords replacing point of care.

Proponents of POCT justify the huge difference in cost -for instance, $0.22 on a chemistry analyzer versus several dollars on a handheld device for blood glucose testing - with the argument that POCT reduces the number of patient visits to the physician's office. In reality, results of most tests available in POCT format could be given over the telephone 24 hours later without any compromise in patient care.

In the hospital setting, interest in pneumatic tube systems is reawakening. Technologic improvements have eliminated some of the drawbacks that previously plagued these devices. A hospital equipped with a state-of-the-art pneumatic tube system can save money and maintain more stringent compliance with quality control standards, while still providing results within an acceptable time frame, by forgoing POCT in favor of traditional laboratory analysis.

The number of tests ordered and their timing is likely to change as well. In the current scenario, the physician orders a huge battery of tests, looks for results that are out of range, and then considers possible diagnoses in greater depth. HMOs and networks are already calling for revision of this standard operating procedure. One alternative is for the physician to order a narrow band of relatively inexpensive screening tests designed to pick up problems in the organ system he or she suspects as the root of the patients' problem. The laboratory then automatically follows up on any abnormal finding with the most sophisticated tests available. Proponents say such a system is a best-of-both-worlds compromise, controlling cost and yet taking advantage of the latest technology where appropriate. Ideally, the laboratory will transcend its role as a commodity provider - in which the commodity is a vast quantity of data - in favor of integration as a provider of meaningful information in the patient management process.

NO BUSINESS AS USUAL

To adapt to this evolving market, IVD manufacturers must rethink their long-range business plans and market strategies. Business growth, traditionally driven by new products, now depends to a much greater extent on market access and competitive pricing. Pharmaceutical companies are already leading the way, investing in distribution channels and generic divisions, reducing the size of their sales forces and focusing on core markets even when such a move requires the jettisoning of profitable nonpharmaceutical businesses.

Negotiating huge contracts with managed care providers will require fewer but much more sophisticated salespeople. A completely different type of account representative, one who can provide a great deal of service and training, may be the key to maintainng an ongoing relationship with a large client. The largest IVD manufacturers will therefore most likely benefit by cutting their sales force. A second tier of IVD manufacturers, smaller than the top ten, will suddenly find themselves able to compete effectively with the former giants.

Options available to the smallest IVD manufacturers will change as well. Agreements with distributors, whose sales forces as a whole lack the depth of knowledge necessary to do business with the large-volume customer, may be less attractive than OEM partnerships.

Like pharmaceutical companies, IVD manufacturers will profit by focusing on core markets. They have too often flooded the market with copycat products, diluting the opportunity for profit in attempts to encroach on the niches of their competitors.

As IVD manufacturers reposition themselves to survive in a rapidly evolving market, they must abandon product development paths mapped out according to past perceptions. Short term goals and customer fads, including POCT and menu consolidation, distract from the big picture: cost effectiveness.

Robert Bauer is a managing partner of CaseBauer and Associates, a Dallas-based consulting and market research firm specializing in in vitro diagnostic markets. He is a member of the editorial advisory board for MD&DI's IVD Technology.

CASEBAUER
Business Development and Research

Improving the Chances of Success in New Product Development

Messenger, 1999

Getting a new product from the drawing table to the lab bench has never been easy. More often than not. efforts are frustrated by delays, cost overruns and reliability problems. With the tightening of profit margins in the 1990's, new product development will be tougher than ever. In the decade ahead, there will be little room for errors in design, timing or cost. New product development —like everything else —will simply have to produce more for less.

Improving the chances for success depends as much on marketing as it does on R&D. Marketing talent and resources can no longer be reserved for the latest stages of development and product launch. Some of the most important contributions marketing can make to a new product occur long before it reaches the launch stage.

Here are just a few ideas of how marketing can improve the chances for new product success by getting more involved in the product development process.

1. Turn Product Concepts Into Product Opportunities

Hundreds of decisions are made in the process of developing a new product. These decisions build upon one another and can often be reversed only at a considerable cost. but they all begin with a product concept.

The product concept ~ a new chemistry analyzer —is not a sufficient base for a successful product launch, however. Marketing can turn that concept into an opportunity by adding more detail. A product opportunity outlines a rationale for the product and clearly describes the customer benefits: it immediately establishes development priorities and guides future decisions.

Be thoughtful in selecting an opportunity target, however. Do your homework. It is the single most important decision made on a product... and it will need to weather many challenges.

Be timely in communicating your thoughts. A development team with upfront knowledge of how you want to position their new product when it gets to market will be much more likely to create a marketable product.

2. Eliminate Non-Critical Product Features

"Do-it-all" product designs attempt to incorporate the best features of every product on the market. In the real world, "do-it-all" designs often don't do enough. They result in "me-too" products that enter the market too late or lackluster products that offer no significant benefits. In short, asking for too much actually can produce too little,

Forget about do-it-all designs and perfect products. Instead, focus on outperforming the competition in areas that are truly important to the customer,

Balance the customer needs with a realistic appraisal of the marketplace and your corporation. including:

Competitive Evolution —what is on the market today and how fast are things changing?

The State of the Art —do your product requirements push or exceed existing technology?

Corporate Strengths —does the new product align with the proven expertise of your corporation?

By identifying critical features, marketing can fine tune product design and help the development team select the basic requirements necessary to meet business objectives.

Clinical Laboratory News

3. Create an Early Vision of the "Final" Product

Most participants on a development team are responsible for only a small pan of the final product; Mechanical engineers design mechanisms. chemists design reagents; software engineers - and so on. Each of these groups faces unique challenges and uses different problem-solving techniques. They often enter the development process at different times. This is not unlike different vehicles leaving different countries at different times with the hope of meeting at some point in the middle of the ocean.

In both cases- success depends on a map and good communication tools. For new product development, the design goal document can serve these functions.

A good design goal document has three characteristics. The first is completeness - Two or three lines is not enough. Work out all the details. For an automated analyzer, this document could easily be 25 pages long.

Next , a rationale, Why a 100-test kit? Is it the common size? Is it the number of tests done in one day? Is it the number of tests done before the reagents expire? If you establish "rationale" early on, many tradeoffs and alternate implementations can be considered without necessarily sacrificing important product benefits.

Finally, an understanding of the "spoilers." Spoilers are features that will make your product unacceptable no matter what else it has going for it. Overnight incubation would definitely be a spoiler for a pregnancy test. Other spoilers might be excessive cost-per-test or a procedure with too much hands-on time.

Marketing can use a design goal document to create a vision of the final product and to guide the product team toward that target.

4. Start at the Beginning... Where it Counts

Late in the development game. options are extremely limited. A change that may have had minimal impact early on could devastate the project at a later stage. If marketing wants to influence what the final product looks like. they need to get involved with R&D right from the start.

5. Become Part of the R&D Process

New product development groups evolve into a close-knit team. They share a common goal. They solve problems together. They challenge one another. They gain each others' respect and trust. As time goes on. the communication level inside the group differs from the communication with outsiders. Within the group, there are few surprises; others may not be so well-informed.

When marketing is close to the R&D process, it can anticipate or learn about issues early and provide timely and accurate feedback. This can help to head off mistakes and avoid delays and setbacks caused by lack of information. In too many cases, effective communication to and from the group is difficult.

To be a part of the process, you must be a part of the team.

6. Make An Effort to "Cross-Communicate"

In most new product groups, there is no common language. The engineers, scientists and the marketers each come to the table with very different expectations. Marketers who make an effort to translate their needs into language that others will understand are much more likely to get their ideas assimilated into the final product design.

This task is easier said than done. If you want an analyzer that is twice as fast as the competition. for example, expect questions such as "how do you measure speed?"; "in random access or batch?"; "which analytes?"; "best case or worst case?"; and "how much can we increase the manufacturing cost?"

To answer the question, the mechanical engineer will need to know all assay protocols to design the mechanism, the scientist will then need to know., etc., etc. The list is endless.

Be careful not to misinterpret these questions as a failure to take responsibility or a "run around." Systems are complex. Communications about systems are even more complex. It lakes time to communicate in a way that is meaningful.

7. Exploit Good Industrial Design

Good industrial design can go a long way toward communicating the attributes of a product to the customer. Time spent designing the produces human interface so that it reflects the produces capabilities will communicate more effectively than any sales brochure. "Easy-to-use" instruments should have self-explanatory keyboards. "Low-cost" reagents should not be in four-color boxes.

Conversely, poorly designed features may make selling tougher and may have to be explained away. Since a human interface design must be done, why not get involved and make it a part of the marketing campaign?

8. Set Up a Jury to Help Evaluate Marketing Decisions

There are two good reasons to establish a system for decision review.

First, the development process is so diverse, no one person can be best qualified to make all decisions.

Second, if you establish yourself as an expert, the team will either design the product to meet your needs (instead of the customers) or they will begin to discount your decisions as opinions.

By using customer consultants, focus groups and other impartial audiences, marketing can get the development team invested in an upbeat, market-oriented process.

9. Anticipate Change

Unless the market is totally stable or you have the uncanny ability to predict the future, you will have to deal with change at some point in the development process. Unanticipated change can be ugly, particularly at late stages in the development cycle.

You can reduce risks of change by identifying the three or four areas where change is likely to impact your competitive position. For example. you may believe that "closed tube" sampling does not justify the added reliability burden and time cost. Its absence "could" become a very significant liability if regulatory guidelines change. however. Therefore, the instrument could be designed with this feature as an option later. More importantly, design decisions that will eliminate the possibility of ever incorporating their capability in the product can be avoided. Often this is no problem if identified early.

You can help hedge the bet. Very few major changes develop overnight.

10. Avoid "Creeping Elegance"

Over time. the new product development process lakes on a life of its own. It is easy for the team 10 get caught up in the excitement of new technology and "add-on" possibilities. Including more "bells and whistles" can be very tempting.

Nobody on the team is in a better position than marketing to put a lid on these elegant extras. You're going to pay for them in some way so if in doubt say "No."

A very long time ago. Machievelli said, "There is nothing more difficult to plan. more doubtful of success, nor more dangerous lo manage, than the creation of a new system." He could have been talking about new product development. There is simply no way to avoid every setback or problem associated with such a complex undertaking. More marketing involvement, however, may go a long way toward improving the chances of success.

Next time you evaluate the costs of having an active marketing participant on a major development program, remember to look at the economics of product failure and product delays.

CASEBAUER
Business Development and Research

Will Healthcare reform of the 90's be more significant than the DRG's of the 80's?

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Achieving economies in the U.S. healthcare market is currently an acute social/political priority as payers, providers, and suppliers scramble to respond to industry and government healthcare reform initiatives. While it is not clear what "reforms" will be legislated, it is absolutely clear that these recent initiatives have catalyzed and accelerated a transformation that has been in the making for at least a decade.

This is not a passing, isolated domestic phenomenon. Worldwide, there are increasing concerns about medical expenditures as the cost of healthcare in more and more countries approaches or exceeds 10% of the gross national product. The US is certainly among the most concerned as it's expenditures lead the pack at 14%. And the problem is worsening as:

- growth of the elderly or "medically intensive" age bracket as a percent of the population; and the increased sophistication of medical technologies are driving costs up, and
- the desire and ability of economically strained governments and industry to absorb the financial burden of "healthcare" is diminishing.

These are long term trends confronting the US and most of the major industrialized nations. While "reform" is now at the center of the US political stage, it should be kept in perspective that it is just one more in a series of reforms to stabilize and / or shift health care costs.

THE IMPACT OF DRG REIMBURSEMENT

During the mid-1980s, DRGs were used to attack steadily rising healthcare costs by decreasing hospital inpatient revenues. DRG based reimbursement and the subsequent reaction of the private insurers resulted in a 27% decrease in hospital days per capita. While it's arguable whether overall healthcare costs were actually curtailed, it is clear that the hospital industry experienced a dramatic change...

- 500 hospitals closed (7%) between 1983 and 1992... slowing the growth of IVD revenues and changing the character of institutional customers;
- an additional 400 hospitals (6%) were consolidated spurring the growth of commercial hospital chains, such as Humana and Hospital Corporation of America, which created a more savvy and price sensitive volume buyer; and
- 450 "true" GPOs and hospital alliances emerged, such as the Voluntary Hospitals of America, SunHealth and AmeriNet, with many vying for position with member hospitals; often promising manufacturers volume purchase opportunities but providing insufficient guarantees, thereby requiring manufacturers to both "work with" and "work around" their

systems to be successful.

Much of the impact of "change" was absorbed by the providers with mostly secondary effects on their suppliers. The net effect on the IVD industry after 8-10 years was an overall slowing of growth as manufacturers adjusted to a reduction in the number of institutional customers, complications in the buying process (changing the actual buyer and buyer roles within the purchasing site), and increasing price pressures.

MANAGED CARE CUTS DEEPER

Managed care is emerging as the "reform" of the 1990's. It is widely known that the Clinton plan favors "managed care" groups. And, based on recent growth, it appears that U.S. industry has already discovered and is embracing HMOs, and PPOs as a cost management and control venue.

Clearly, the advantage of managed care groups lies in their ability to tackle "healthcare" cost on a broader front, and thereby minimize the propensity to cost shift... the recognized shortcoming of DRG based reimbursement. And managed care companies are gaining a reputation of not only being tight fisted, but as being the leaders in the development of tools to manage costs down. For example, some of the most sophisticated managed care payers and providers already have the information systems and experienced staff to attack their pharmacy costs with methods such as:

- controlling price through discounts, contracts and capitation agreements;
- controlling volume with closed formularies and drug utilization/medical procedure reviews; and
- restricting demand by prohibiting sales reps from calling on member physicians and even "counter detailing" member physicians to combat pharmaceutical marketing messages that may conflict with established formulary policies.

We are still early in the evolution of managed care and, so far, hospitals and physicians are bearing the brunt of this reform as they compete with each other to obtain the captive patient populations of various managed care plans... usually under stingy capitated rate agreements.

However, unlike DRG based reimbursement, the impact of managed care already promises to extend well beyond providers (hospitals and physicians) and encompass their health care product suppliers as well.

This is apparent in the pharmaceutical industry with the growth of commodities/generics, changes in market access strategies, the restructuring marketing/sales organizations, and the reorientation of price and strategies.

We are already seeing the pharmaceutical industry beginning to make fundamental changes in the way it does business. For example:

- Lilly is jettisoning profitable non-pharmaceutical businesses to provide the resources and focus required to restructure its pharmaceutical core;
- beginning with Marion Merrell Dow's buyout of Rugby-Darby's generic business and Miles' recent purchase of a minority interest in Schein Pharmaceutical, the trend is for manufacturers of brand-name products to invest heavily in generics - either through buyouts or by establishing their own generic subsidiaries. Wyeth-Ayerst, Rhone-Poulenc Rorer, Merck, Upjohn, and Zeneca have all recently started their own generic units. The trend is spurred by drug companies' desire not only to seek an edge with managed care purchasers but to retain as much revenue as they can from products with patents that are about to expire; some companies have begun to construct new means of market access. Most notably, in a $6 billion deal, Merck acquired Medco Containment Services last July, a pioneer

of mail order distribution in the managed care environment; and
- Marion Merrell Dow became the first in the industry to cut its sales force in an effort to adapt to the changing environment when it announced an 18% reduction last summer. Syntex followed close behind with an announced 13% reduction.

WILL IVD BE EXEMPT?

The fact is, the diagnostics industry has not yet been challenged as aggressively as the medical/surgical and pharmaceutical industries by these same managed care companies. But this is not necessarily a reprieve.

As should be expected, priorities have been focused on bigger ticket items such as hospitalization (length of stay) and physician expenses. Pharmaceuticals are a bit further down the line... and diagnostics still further down the line.

Diagnostic tests have been a lower priority than pharmaceuticals for good reason.

First, at 4% of the total healthcare spending, they represent less than half of the total US healthcare premium for pharmaceuticals.

Secondly, there is much less "profit" to be wrung out of the diagnostic manufacturers:

- unlike pharmaceuticals, diagnostic tests aren't protected by patents (generally) and do not command extreme "premiums";
- hospital and reference laboratories have been relatively cost conscious buyers since the advent of the DRG system in the mid-late 1980's and have "shopped down" the excesses in the market; and
- the diagnostics industry is over-capitalized in general, and manufacturers have been competing fiercely for survival.

And, third, unlike pharmaceutical costs which are largely outside product costs, fully two-thirds of diagnostic testing costs are inside costs for labor and facilities. This means that the product portion of diagnostics is less than 1% of healthcare spending in the US or 1/10 of that of pharmaceuticals.

Furthermore, there are numerous other tactical issues that when taken as a whole, complicate and hinder a more rapid transformation of the laboratory market (such as the investment in physical plant and the cost of prematurely retiring capital equipment).

But just because it is not "in your face" today, don't be lulled into thinking its not going to happen. The effects of these long term health care trends are now coming into focus and need to be an integral part of your marketing planning .

As managed care covers a greater percent of the "insured population"... as providers become more sophisticated about their costs and more sophisticated with their tools... the "managed care" impact on diagnostics will likely be more significant than anything we experienced under "DRGs".

Robert Bauer is a Director with CaseBauer & Associates, a Dallas based business development consulting and marketing research firm specializing in In Vitro diagnostic markets, worldwide.

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Main Office
The Towers at Williams Square
5215 North O'Connor Blvd.
Suite 1785
Irving, Texas 75039

Voice: (972) 869- 2500
(888) 357-7481
Fax: (972) 432- 9042
(888) 357-7519

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