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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Another Portent Of Change

How many laboratory executives and pathologists consider themselves futurists? Probably not many, because healthcare's traditional fee-for-service arrangements provided little financial incentive to alter the status quo.

Yet I would argue that the radical restructuring of healthcare currently underway demands that laboratory executives acquire the talent for anticipating the future. In 1992, how many laboratory executives expected managed care to rapidly grow to as much as 50% to 60% of their revenue base in five years?

Obviously not many, because the laboratory industry willingly offered capitated rates which barely covered marginal costs. Did these same executives anticipate the growth of managed care Medicaid programs, or the absolute declines in Medicare reimbursements which the industry was forced to endure? The evidence says they did not. Financial effects from this lack of foresight are now visible. In California, **Physicians Clinical Laboratories** entered Chapter 11 bankruptcy and the financial decline of **Unilab** is well known.

Among the national chains, **Corning Incorporated** was forced to divest what, in rapid order, was called **Metpath**, then **Corning Clinical Laboratories** and now **Quest Diagnostics Incorporated**. **Laboratory Corporation of America** currently struggles to keep almost $1 billion of unhappy lenders away from their door. Now that the financial consequences from this lack of foresight have been realized, I'll bet these laboratories, armed with 1997's 20-20 hindsight, would have priced managed care services differently in 1992.

The fact that commercial laboratories did not accurately predict the future has brought that segment of the industry to a financial crisis. What commercial laboratories look like in 24 months will be very different from what they are today. The lack of accurate foresight about capitation prices is precisely the example I want to use to illustrate the importance of thinking about the future.

In this issue of THE DARK REPORT, you will read one man's predictions about the two major revolutions that laboratory information systems (LIS) must undergo during the next five years. *(See pages 7-12.)* Because all laboratory operations are intensely linked to LIS, the financial success or failure of a laboratory will increasingly depend on whether the laboratory is using an effective laboratory information software program.

But this man's message has an even more important ramification. If coming generations of LIS are to include process control features similar to those used in manufacturing plants, will today's crop of laboratory executives be ready with the knowledge and expertise to use those features to the benefit of the laboratory and the integrated healthcare systems which they serve? TDR

Florida Medicare Carrier Raises Kickback Issues

Pathology laboratory practices singled out as possible violations of anti-kickback laws

CEO SUMMARY: When Florida's Medicare carrier published a notice which defined certain pathology practices to be possible violations of anti-kickback laws, it created uncertainty for labs. DIANON took immediate steps to insure compliance while seeking clarification from regulators on this issue.

Developments in Florida signal that regulators may be preparing to target laboratories for more aggressive enforcement of anti-kickback and inducement laws, possibly on a national basis.

Last fall the Florida Medicare carrier published an advisory on this issue. *(The full text is reproduced on page 3.)* The carrier's action was apparently triggered by complaints from individuals in the state about the business practices of laboratories.

A careful reading of the carrier's advisory indicates that the carrier was made aware of certain laboratory practices. After discussing these practices with the Medicare Fraud Branch, the carrier "determined that the distribution of such materials clearly falls under the definition of 'kickback,' and is therefore illegal." The carrier noted that "to persuade prospective referring physicians to send specimens to certain pathology laboratories... representatives of these labs are giving away certain medical items, such as prostate needles to urologists and cautery instruments to gastrointestinal specialists."

The explicit mention of pathology laboratories, as well as specific collection supplies such as prostate needles and cautery instruments, caught the attention of laboratories serving Florida. **DIANON Systems**, a national provider of pathology services, reacted quickly to the carrier's determination.

"When this surfaced last November, we responded with two actions," stated Kevin Johnson, President and CEO at DIANON. "First, in December we informed our physician clients in Florida of the Medicare

carrier's ruling and we stopped providing the collection supplies affected by this Medicare advisory.

"Second, we wrote the **Office of the Inspector General** (OIG) and requested clarification from them on this specific issue," explained Johnson. "Our attorneys tell us that supplies used solely for the collection and transport of specimens are clearly within the law. We do not know why the Medicare carrier in Florida interprets this differently.

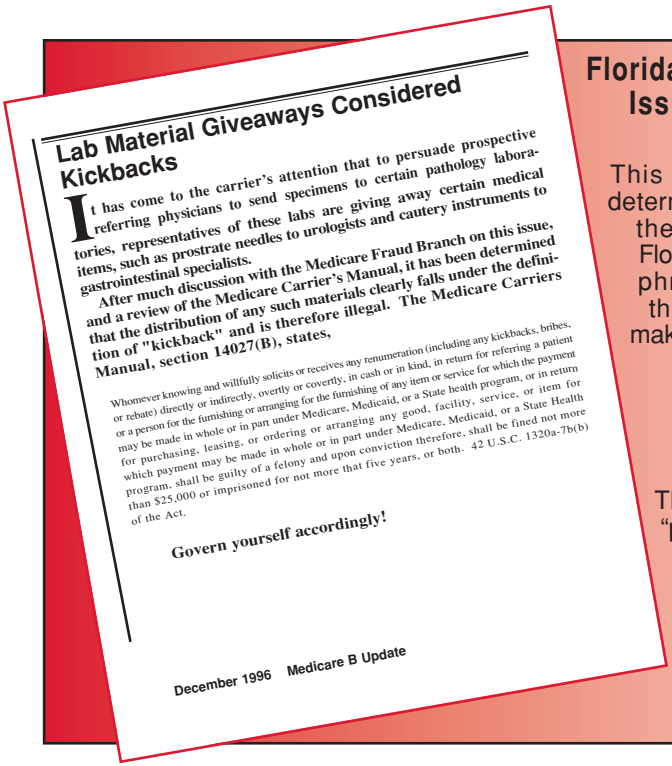
"From what we can determine, it appears this was initiated at the state level. To our knowledge, there was no input from the federal level. That is why we wrote the OIG and asked for their ruling on this issue."

Since DIANON sent their letter to the OIG in December, they have heard nothing. "While waiting for the OIG opinion, we considered it prudent to cease the practice in question until the OIG provides definitive guidance not only in Florida, but nationwide," said Johnson. "We made that decision in February. In March we sent letters to all our physician clients throughout the United States announcing this decision." *(The full text of the letter is reproduced on page 4.)*

DIANON's legal department also provided other laboratories operating in Florida with a copy of the Florida Medicare carrier's interpretation of anti-kickback statues. Should the Florida carrier's determination be affirmed by federal regulators, it will have a significant impact on the business practices of laboratories.

Unintentional Reassessment

It is the opinion of THE DARK REPORT that the action by the Florida Medicare carrier may have uninten-



Lab Material Giveaways Considered Kickbacks

It has come to the carrier's attention that to persuade prospective referring physicians to send specimens to certain pathology laboratories, representatives of these labs are giving away certain medical items, such as prostrate needles to urologists and cautery instruments to gastrointestinal specialists.

After much discussion with the Medicare Fraud Branch on this issue, and a review of the Medicare Carrier's Manual, it has been determined that the distribution of any such materials clearly falls under the definition of "kickback" and is therefore illegal. The Medicare Carriers Manual, section 14027(B), states,

Whomever knowing and willfully solicits or receives any remuneration (including any kickbacks, bribes, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or a person for the furnishing or arranging for the furnishing of any item or service for which the payment may be made in whole or in part under Medicare, Medicaid, or a State health program, or in return for purchasing, leasing, or ordering or arranging any good, facility, service, or item for which payment may be made in whole or in part under Medicare, Medicaid, or a State Health program, shall be guilty of a felony and upon conviction therefore, shall be fined not more than $25,000 or imprisoned for not more that five years, or both. 42 U.S.C. 1320a-7b(b) of the Act.

Govern yourself accordingly!

December 1996 Medicare B Update

Florida Medicaid Carrier Issues Anti-Kickback Determination

This is the anti-kickback determination as issued by the Medicare carrier in Florida last fall. Use of the phrase "it has come to the carrier's attention," makes it appear that complaints about certain business practices caused the carrier to rule on the laboratory practices at issue.

The specific mention of "pathology laboratories" as well as collection devices common to tests offered by pathology laboratories would seem to confirm this fact.

tionally triggered a reassessment by federal prosecutors of how to define anti-kickback and inducement statutes as they apply to current laboratory industry business practices.

Preliminary investigation by THE DARK REPORT indicates that competing physicians may have been the ones who brought the collection supply issue to the attention of the Florida carrier. However, once the Florida carrier published their determination that providing certain collection supplies violated anti-kickback statutes, then the "law of unintended consequences" may have taken effect.

Currently the OIG has a more skeptical attitude toward the clinical laboratory industry than was true seven years ago. The OIG also has a sophisticated understanding of laboratory business practices, gained through almost five years of intense investigations.

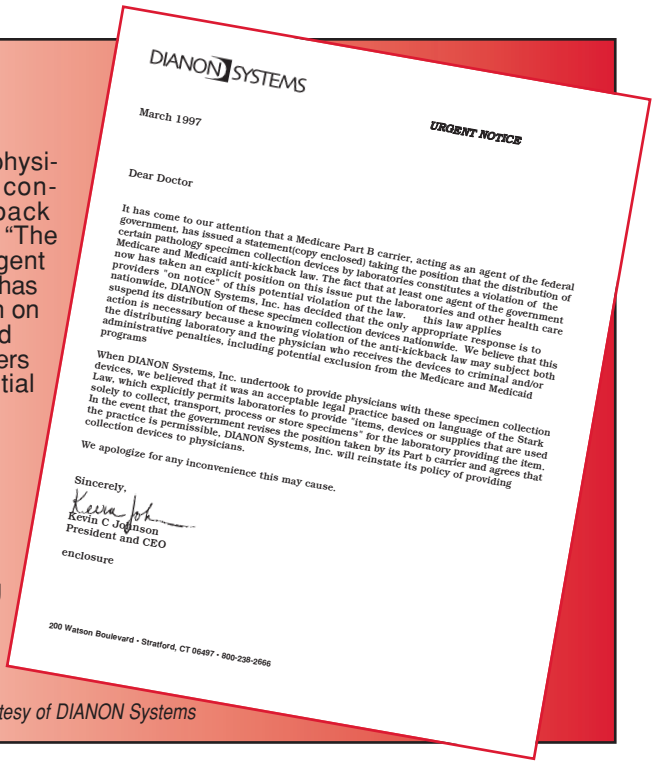
It would be reasonable to assume that the actions of the Florida carrier, and a laboratory's request for a binding opinion, are causing federal regulators to determine whether they want to "redefine" certain laboratory business practices as kickbacks or inducements.

THE DARK REPORT noted in earlier issues that the federal settlement with **SmithKline Beecham Clinical Laboratories** for $325 million included allegations of inducement between the laboratory and physician clients. That could be considered both a precedent and current evidence of how federal prosecutors view enforcement of kickback and inducement laws affecting laboratory practices.

Dianon Systems Alerts Physicians

This is the letter which DIANON sent to their physician clients nationally concerning the anti-kickback statute. It covers how "The fact that at least one agent of the government now has taken an explicit position on this puts laboratories and other health care providers 'on notice' of this potential violation of the law."

It should not be overlooked that physicians are equally culpable under the anti-kickback law. By providing notice to the physicians, DIANON is informing them about a situation of which they would otherwise be unaware.



DIANON SYSTEMS

March 1997

URGENT NOTICE

Dear Doctor

It has come to our attention that a Medicare Part B carrier, acting as an agent of the federal government, has issued a statement(copy enclosed) taking the position that the distribution of certain pathology specimen collection devices by laboratories constitutes a violation of the Medicare and Medicaid anti-kickback law. The fact that at least one agent of the government now has taken an explicit position on this issue put the laboratories and other health care providers "on notice" of this potential violation of the law. this law applies nationwide. DIANON Systems, Inc. has decided that the only appropriate response is to suspend its distribution of these specimen collection devices nationwide. We believe that this action is necessary because a knowing violation of the anti-kickback law may subject both the distributing laboratory and the physician who receives the devices to criminal and/or administrative penalties, including potential exclusion from the Medicare and Medicaid programs

When DIANON Systems, Inc. undertook to provide physicians with these specimen collection devices, we believed that it was an acceptable legal practice based on language of the Stark Law, which explicitly permits laboratories to provide "items, devices or supplies that are used solely to collect, transport, process or store specimens" for the laboratory providing the item. In the event that the government revises the position taken by its Part b carrier and agrees that the practice is permissible, DIANON Systems, Inc. will reinstate its policy of providing collection devices to physicians.

We apologize for any inconvenience this may cause.

Sincerely,

Kevin C Johnson
President and CEO

enclosure

200 Watson Boulevard • Stratford, CT 06497 • 800-238-2666

Letter courtesy of DIANON Systems

It would be reasonable to assume that federal regulators already consider many laboratory business practices to be borderline violations of inducement and kickback laws. Regulators would base this on their 1997 perspective, while looking to enforce this reinterpretation of the law on a retrospective basis.

The OIG's lengthy silence without a ruling may be related to the newly-announced policy of providing advisory letters. But three factors make THE DARK REPORT believe that federal regulators might be reinterpreting how laboratories comply with inducement and anti-kickback statutes.

Intimate Understanding

First, regulators now have an intimate understanding about laboratory operations. Second, they have confidence, gained from successful Medicare fraud settlements with laboratories. Third, if federal investigators weigh the financial and publicity benefits of changing how anti-kickback and inducement statues are interpreted and enforced, they might decide that they have a financial and public relations bonanza. It would be a low-risk, high-return strategy.

It is speculative to assume that federal regulators may indeed choose this course of action. However, it has been 90 days since DIANON requested an opinion from the OIG. Since no reply is forthcoming, that is evidence that serious debate could be taking place among regulators.

In the meantime, DIANON should be recognized for taking positive steps to comply with the carrier's interpretation while seeking definitive guidance from the OIG. Although these steps placed the company at a competitive disadvantage, the long-term interests of DIANON's stockholders, employees, physicians and employees were well served by this prudent action. **TDR**

(For further information, contact Kevin Johnson at 203-381-4000.)

California Labs Play With Fire On Issue Of Inducements

Contrast DIANON's response to a regulatory ruling on anti-kickback practices with those of California laboratories responding to state inducement laws.

DIANON, although not in agreement with the carrier's ruling, immediately wrote the OIG requesting clarification. Meanwhile the company ceased the practices in question, despite possible competitive disadvantages. This is good corporate citizenship. It is also smart compliance.

*In California, laboratories do not dispute that state law prohibits inducements, such as the placement of phlebotomists in a physician's office. (*See TDR, July 1, 1996.) *Yet, even after the* ***California Clinical Laboratory Association*** *sent out copies of the legislative council's legal opinion and a* ***Department of Health Services*** *letter declaring the practice illegal, no major laboratory has ceased the practice.*

This brings about an interesting question: whenever the first state prosecution singles out a California laboratory for civil or criminal action, what defense can that laboratory offer? It is certainly on public record that they were given notice that the practice violated the law.

California laboratory executives should expect no sympathy or mercy whenever state prosecutors finally decide to enforce an outstanding law. At that time they may wish they had followed DIANON's conservative example of regulatory compliance.

Meditech & LabSoft Top 1996 LIS Sales Rankings

Meditech dominates hospital LIS activity, LabSoft has big year with independent labs

CEO SUMMARY: Turnover and turmoil are the big news in the LIS field. Hospitals and commercial laboratories are upgrading or replacing their existing LIS software at a rapid pace. Meanwhile, mergers and consolidations within the LIS industry create new power players. LIS conversion projects continue to be difficult, expensive and time-consuming.

Market leaders **Meditech** and **LabSoft, Inc.** topped THE DARK REPORT's rankings of the Top Ten LIS Vendors for 1996. Meditech and LabSoft ranked number one in both new sales and total installations in the categories of hospitals and non-hospitals, respectively.

Meditech sold 82 new systems to hospitals during 1996. **Shared Medical Systems** (SMS) and **Sunquest Information Systems** tied for second place. Each sold 54 new systems in 1996.

LabSoft, Inc. sold 142 systems to non-hospital laboratory sites during 1996. Trailing at number two and number three were **Schuyler House**, with 33, and **Clinical Information Systems**, with 28.

Meditech and LabSoft also topped the rankings for total installed systems in their respective categories of hospital and non-hospital.

With 741 installed hospital LIS systems, Meditech has a significant lead over the 609 installations of number two ranked Sunquest. **Cerner Corporation** comes in third, with 490, trailed by **Citation Computer Systems** at 486 and **HBO & Co.'s** 411 installations.

For non-hospital laboratory installations, LabSoft's 675 installations were more than double **Comtron's** 265 installations. Sunquest came in third with 256 non-hospital LIS installations.

Meditech's large numbers of sales and installations are generated from its contract with **Columbia/HCA**. It is the exclusive information systems vendor for all hospitals owned and operated by Columbia.

Meditech's large numbers of sales and installations are generated from its contract with Columbia/HCA.

THE DARK REPORT's annual Top Ten LIS Vendor rankings aid laboratory executives in watching how the marketplace judges products offered by different LIS vendors.

The most visible industry change during 1996 was an increasing number of acquisitions. The large transaction was **Sunquest's** acquisition of **Antrim**. **Dynamic Healthcare Technologies** purchased **CoMed** and gained rights to

CoMed's popular anatomic pathology product, called CoPath. **Isys** purchased **Biovation**.

Impact From LIS Mergers

"These mergers have the potential to impact many laboratories during the next two years," stated Raymond Aller, M.D., Professor of Pathology and of Medical Informatics at the **University of Utah**. "Take the Sunquest-Antrim merger, for example. Antrim was clearly one of the two leading laboratory vendors among commercial laboratories. Now it is joined with Sunquest, which is a market leader in its own right in providing hospital LIS systems.

"If the combination of these two companies works successfully," he continued, "they could provide laboratories with LIS resources which exceed what each company could do alone."

Dr. Bruce Friedman agreed. "Consolidation of LIS companies is the big story of 1996. When your LIS vendor gets bought by a new company, you do not know whether the new owner will change things for the better or for the worse."

Dr. Friedman is the Director of Pathology Data Systems and Ancillary Systems at the **University of Michigan Medical Center**. He is a keen observer of the LIS world and pointed out the potential downside from 1996's mergers.

"When you buy a software company, you are really buying intellectual capital," he explained. "If the acquired company had a good product and a good service team, many times the new owners end up driving those people assets away. This can cause a rapid deterioration in both service and the quality of the product."

"Consolidation among LIS vendors should be expected," said Dennis Winsten, president of **Dennis Winsten**

THE DARK REPORT'S Top Ten LIS Vendors
Hospital New Sales (1996)

Rank	Company	Total New Sales 1996	Cumulative New Sales	New Sales Per Cent	Cumulative Per Cent
1	Meditech	82	82	15.39%	15.39%
2 Tie	Shared Medical Systems	54	136	10.41%	25.80%
2 Tie	Sunquest Information Systems*	54	190	10.41%	36.21%
4	Citation Computer Systems	38	228	7.13%	43.34%
5	HBO & Co.	36	264	6.76%	50.10%
6 Tie	Laboratory Consulting, Inc.	30	294	5.63%	55.73%
6 Tie	Soft Computer Consulting	30	324	5.63%	61.36%
8	Fletcher Flora	24	348	4.51%	65.87%
9	Cerner Corp	20	368	3.76%	69.63%
10	CPSI	17	385	3.19%	72.82%
	Total All (45) Vendors: New Sales	533		72.82%	

*Includes Antrim

Provided by: R.L. Johnson & Associates

& Associates, a recognized consultant specializing in healthcare-based information systems. "The marketplace served by LIS vendors is dwindling. In the commercial laboratory area, consolidation is over.

"It is a similar story with hospital laboratories. Widespread mergers between hospitals, accompanied by a general decline in the occupancy rate of hospitals, reduce the number of sites which need LIS," he continued. "Sales numbers and earnings of the LIS vendors reflect this. In fact, most of the new sales reported by these companies are LIS conversions, where hospital labs which were using Vendor A switch to Vendor B and vice versa."

Numbers used by THE DARK REPORT were gathered by **R. L. Johnson and Associates** of Danville, California. Johnson has collected annual data from hospital software vendors for 15 years. Like Winsten, he believes that LIS vendors face a shrinking laboratory marketplace. Revenue growth will not come from placing more installations. Instead, it will come from providing software products which offer unique and useful features.

Last year Winsten told THE DARK REPORT that LIS systems were increasingly driven by the need to provide cost and productivity data along with the normal functions of test analysis and reporting. He also predicted technology changes to hardware and software would lead to decentralized data processing departments.

"Managed care is driving the requirement for LIS to provide more sophisticated cost and productivity reports," said Winsten. "Those elements are creeping into the various LIS software packages. However, over the course of 1996 I did not see LIS vendors introduce many additions to functionality."

THE DARK REPORT'S Top Ten LIS Vendors
Hospital Installations (1996)

Rank	Company	Total Installed	Cumulative Installed	Installed Per Cent	Cumulative Per Cent
1	Meditech	741	741	16.13%	16.13%
2	Sunquest Information Systems*	609	1,350	13.25%	29.38%
3	Cerner Corp	490	1,840	10.67%	40.05%
4	Citation Computer Systems	486	2,326	10.58%	50.63%
5	HBO & Co.	411	2,737	8.95%	59.58%
6	Soft Computer Consulting	268	3,005	5.84%	65.42%
7	Isys/Biovation	236	3,241	5.14%	70.56%
8	Laboratory Consulting, Inc.	170	3,411	3.70%	74.26%
9	Creative Computer Applications	160	3,571	3.49%	77.75%
10	Soft Computer Consulting	133	3,704	2.90%	80.65%
	Total All (45) Vendors: Installations	4,596		80.65%	

*Includes Antrim

Provided by: R.L. Johnson & Associates

"In fact, probably the most notable change for LIS users during 1996 was the arrival of the graphical user interface (GUI) to LIS. This utilizes the Windows' 'point and click' approach to software. It is rapidly becoming a standard feature for LIS.

"Another area which surprises me is the resurgence of stand-alone anatomic pathology and blood banking systems," mused Winsten. "Laboratories seem willing to purchase the stand-alone software module if the variety of features appeals to them.

"One specific area where rapid change is occurring to LIS involves bet-ter front-end architecture. Although this is invisible to laboratory LIS users, vendors are quickly incorporating new computer hardware and new software technology into their LIS programs. This makes it easier and faster for them to enhance the future capabilities of their LIS software."

Winsten made another interesting comment about the collective capabilities of the existing LIS software products currently available. "With the trend toward regional laboratory networks, I am not convinced that there are any LIS products which are designed to meet the unique needs of regional laboratory networks."

Regional Lab Networks

"Unlike a multiple hospital laboratory information system, a regional lab network usually consists of a loose coalition of hospital laboratories," noted Winsten. "Thus, the LIS requirements of regional laboratory networks are different from the LIS requirements of multiple laboratory sites within an integrated healthcare system."

Winsten's observation reveals a recognition that the growing national movement toward regional laboratory networks will encounter problems if no satisfactory LIS software product is

THE DARK REPORT'S Top Ten LIS Vendors
Non-Hospital New Sales (1996)

Rank	Company	New Sales 1996	Cumulative New Sales	New Sales Per Cent	Cumulative Per Cent
1	LabSoft, Inc.	142	142	39.67%	39.67%
2	Schuyler House	33	175	9.22%	48.89%
3	Clinical Information Systems	28	203	7.83%	56.72%
4	Comtron	25	228	6.99%	63.71%
5	Fletcher Flora	16	244	4.47%	68.18%
6	Hex 'FF'	13	257	3.64%	71.82%
7	Computer Services & Support	11	268	3.08%	74.90%
8	Isys/Biovation	10	278	2.80%	77.70%
9 Tie	Citation Computer Systems	8	286	2.24%	79.94%
9 Tie	Intellidata	8	294	2.24%	82.18%
	Total All (45) Vendors: New Sales	358		82.18%	

Provided by: R.L. Johnson & Associates

developed to meet the unique needs of such networks.

What might be the next hot thing for LIS? Dr. Friedman believes the surprise answer will be LIS systems built around internet browser technology, using the emerging technologies of "fat client" and "thin client."

"What often gets overlooked in discussions about what LIS can and should do is the underlying cost of maintenance," he said. "Hospital IS managers have increasingly relied on desktop computers. Yet the average cost to maintain and service a desktop computer now approaches $6-$8,000 per year. This "thin client" technology basically pares down the amount of software that the desktop computer uses.

"Instead of loading all the software on each desktop computer, there exists a server in the middle tier of this system. Virtually no software is resident on the desktop. This drives down maintenance costs because changes and upgrades are only made to the single server in the middle tier of the computer network.

"Also, it means that the desktop computer can be relatively simple, either an Apple or a Wintel," concluded Dr. Friedman. "This technology is catching the attention of information systems managers in all industries, not just healthcare. I believe it will rapidly find its way into laboratory information systems.

"Further, this technology is well suited for use by the 'virtual laboratory," he concluded. "It enables remote testing sites to be economically linked to the central LIS." TDR

(For further information, contact Raymond Aller, M.D. at 801-581-7249, Bruce Friedman, M.D. at 313-764-8333 and Dennis Winsten at 520-290-9989.)

THE DARK REPORT'S Top Ten LIS Vendors
Non-Hospital Installations (1996)

Rank	Company	Total Installed	Cumulative Installed	Installed Per Cent	Cumulative Per Cent
1	LabSoft, Inc.	675	675	26.61%	26.61%
2	Comtron	265	940	10.45%	37.06%
3	Sunquest Information Systems*	256	1,196	10.09%	47.15%
4	Creative Computer Applications	245	1,441	9.66%	56.81%
5	Isys/Biovation	155	1,596	6.11%	62.92%
6	Hex 'FF'	115	1,711	4.54%	67.46%
7	New Lab Force	99	1,810	3.91%	71.37%
8	Schulyer House	89	1,899	3.51%	74.88%
9	Computer Services & Support	75	1,974	2.96%	77.84%
10	Clinical Information Systems	74	2,048	2.92%	80.76%
	Total All (45) Vendors: Installations	2,537		80.76%	

*Includes Antrim

Provided by: R.L. Johnson & Associates

New Features Slated For Lab Information Systems

Future software versions will incorporate manufacturing "process control" features

CEO SUMMARY: Two processes are transforming healthcare: managed care and quality management. Laboratory information systems must incorporate radically new features if they are to support changes to clinical laboratory operations. This makes it imperative that laboratory executives select an effective laboratory information system.

PARALLEL DEVELOPMENTS in the healthcare marketplace are shaping the design and function of laboratory information system (LIS) software. Radical changes to existing LIS programs will become obvious in the next generation of product releases.

Such radical changes are driven by two dominant influences. First, healthcare providers are quickly integrating clinical pathways. For laboratories, this increases the need to move both raw data and processed information from the laboratory to physicians, hospitals and other treatment centers within the integrated healthcare system or network.

Second, new technology inside the laboratory will require LIS to drive laboratory operations in totally unique ways. LIS will become an essential management tool for laboratory operations.

"These two trends raise the stakes for making the right LIS decision," said Randall Spratt. "By choosing the correct LIS, you position your laboratory to provide 'added value'." This is because your LIS becomes the primary tool for continuous reengineering in response to marketplace changes."

Spratt has unique insight into the future of laboratory information systems. He is Vice President of Product Planning and Development for **Advanced Laboratory Group** (ALG), a division of **HBO & Co.** In this role, he is responsible for identifying specific product features that must go into future versions of LIS. He then develops the actual software product to provide such features.

"These two trends raise the stakes for making the right LIS decision," said Randall Spratt. "By choosing the correct LIS, you position your laboratory to provide 'added value'."

"We must anticipate all changes to laboratory instruments, lab technology and the management organization of the laboratory," he continued. "That's not all. As we design new software to meet the laboratory's needs, we must incorporate a bewildering variety of new, and frequently unproven, computer hardware and software technologies."

Spratt believes that the laboratory industry is about to undergo a major revolution in business thinking and management philosophy. "When we first began designing laboratory information systems ten years ago, we considered clinical laboratories and factories to be virtually identical in purpose and process. We designed laboratory software from that perspective.

"We always believed that any laboratory which applied manufacturing process control features to clinical laboratory operations had a competitive advantage," explained Spratt. "However, only in the last two or three years do we find an increasing number of laboratory directors sharing that view."

Shift In Thinking

"This is an important shift in thinking. It means that economic and service pressures are forcing laboratory directors to look outside the clinical laboratory industry to find proven techniques which can lead to lower costs, improved quality and better laboratory services.

"Because industry has already demonstrated the power of manufacturing process control techniques to lower costs and improve quality," stated Spratt, "it is inevitable that clinical laboratories will adopt those techniques. I predict that process controls will be an essential feature of all future LIS software."

Along with process controls, future versions of LIS software must support integration of clinical data. "Clinical laboratories must recognize that integrated healthcare systems will be organized around full clinical integration. In that environment, the only financially successful laboratories will be those which can effectively contribute to sophisticated clinical integration.

"Although we see full clinical integration as the end game," noted Spratt, "there are still three distinct healthcare models which exist today, and to which laboratories must provide services. Each model imposes different requirements on the laboratory serving that model. Accordingly, LIS needs for each model must have different capabilities.

"The first model is the community-wide managed care plan," he explained. "This is generally an independent insurance plan which contracts for healthcare services across the community. It covers a sizable number of lives and plays a dominant role in that regional market. The various **Blue Cross** plans provide good examples of this model. Such plans are usually served by larger independent commercial laboratories such as **Quest Diagnostics** or **Laboratory Corp. of America**.

"In this model, competition among the clinical laboratories is mostly based on price. Geographical service coverage is an issue, but the insurance plan is primarily seeking the lowest price for laboratory services.

"The second model is the acute care organization," Spratt said. "This model evolves from those integrated health systems organized by hospitals. There are two forms of this model. One form is comprised of the 'cradle to grave' system. This is a vertically integrated organization and all providers are generally owned by the system.

"The other form is horizontal. The hospital is acquiring other hospitals, but does not necessarily acquire and own other types of healthcare providers.

"Whichever form the integrated system takes," noted Spratt, "laboratories within the system compete internally. There is the need to integrate data flows between the laboratory sites inside the system and laboratory functions are commonly organized around a 'centers of excellence' model.

"It is important to recognize that the first priority for laboratories within integrated systems is not to add value, but to reduce excess costs. At this stage in the laboratory's evolution it is an 'order

filler.' The strategic flow of information is still unappreciated within the integrated organization.

"The third laboratory model is that of the independent clinical laboratory. Such a laboratory serves a variety of medical service organizations," Spratt remarked. "They can range from large laboratory chains such as Quest to local independent laboratories. Within this model, competition is primarily based on price and services provided to the physician clients."

Value Added

"We believe that laboratory information is the key to 'value added' for laboratories. In the three current marketplace models given above, there is a common evolution toward clinical integration. This clinical integration requires laboratories to pass data throughout the system.

"How important is the laboratory data?" asked Spratt. "You may be surprised to know that a Texas study in the late 1980s looked at the data collected by integrated delivery systems. It determined that, including a patient's financial information, laboratory data was 60% to 70% of the total patient file!

"Further, physicians perceive laboratory data to be as much as 80% of the value in a patient's clinical file," he continued. "For example, diagnostic procedures such as ultra sounds and X-rays may only have value prior to, or immediately after, a (surgical) procedure. But even older laboratory test results probably have ongoing clinical value because they document the patient's response over time to different disease states and therapies."

What Spratt points out is a fact overlooked by laboratory directors. Compared to other forms of clinical data, laboratory test results have a long term value which exceeds most other clinical information. This is precisely the "value added" component which Spratt wants his next generation of LIS software to deliver.

"Market leadership will go to the health system which can move toward a strategic use of clinical data," he predicts. "Only a limited number of reflexive testing pathways, such as hepatitis, are well explored and clinically accepted. In the integrated system of the future, it will be essential to answer the question 'is it reasonable to order a test where you statistically do not know if it improves the clinical outcome?'

"Clinical studies will be used to identify the efficacy of both treatment pathways and laboratory tests. This is how the use of clinical information leads to added value and a competitive edge. I believe laboratories would be well advised to develop expertise and capability in that area now. Since 'state of the art' has not yet been defined, laboratories have an opportunity to develop a competitive edge.

"We also believe that the analysis and process of using this laboratory data will take place independent of the process of collecting and testing the specimens. For that reason, LIS software must easily integrate with the information system of the healthcare organization it serves."

Market Forces

Having outlined the essential market forces driving the integration of clinical data, Spratt turned to the next major revolution in laboratory information systems: process controls. "There is a dichotomy in our view of the laboratory as factory. Two parallel trends shape how process control technology should be used in the laboratory.

"New instruments, automated transport lines, robotics and modular workstation systems are hitting the laboratory marketplace daily," noted Spratt. "Increasingly these instruments and supporting components have data ports which increase the amount of informa-

tion which can be passed to a laboratory information system.

New Capabilities

"These data ports allow the instruments and equipment to report not just test results, but the operating condition of the equipment itself. Think of it like the self-diagnosing capability of car engines. Auto mechanics now plug a diagnostic computer into the engine's data port. Instantly the computer verifies the status of all operating systems in the engine, whether functioning or not."

"Yet, even as the actual testing takes place outside the traditional walls of the central laboratory, there is a continuing need to collect, integrate and report laboratory data..."

"All new generations of laboratory instruments will have the same capability. They will be able to tell a master computer program about their operational status. Is the instrument functioning? Is it calibrated and operating within expected ranges? Is any part of the instrument malfunctioning?

"It is this flow of operational information which enables the LIS to apply process control techniques to the flow of specimens through the laboratory."

The concept of the centralized laboratory is integral to Spratt's analysis of how LIS will incorporate process control functions with its traditional role of data collection and reporting. But Spratt also recognizes early signs of laboratory decentralization.

"Look at what alternative laboratory testing technology promises to offer the clinician: point-of-care, near-patient testing, even home test kits. Each is a technology which moves testing outside the central laboratory. Yet, as actual testing takes place outside the traditional walls of the central laboratory, there is a continuing need to collect, integrate and report laboratory test data to all locations within the healthcare system.

"That is why we are designing new capabilities into our next generation of software. The LIS must handle both process control tasks and data integration. For process control, LIS vendors will work with laboratories to develop 'rule systems' or 'expert systems' which are much more sophisticated that what is currently available.

"Existing software makes basic calculations and alerts the medical technologist for action. Future LIS software will permit more sophisticated action items," he explained. "Where existing LIS now says either yes or no to the result, future LIS systems will automatically identify specimens which require a retest, locate and transport that specimen to the proper instrument, perform the retest and take appropriate steps to achieve a reportable result. Humans will probably only be asked to authorize the final results of any retested specimen.

"Such sophisticated interaction comes with a consequence. When LIS software begins making "decisions," it crosses the line between a library system and a medical device. Now the **Food and Drug Administration** wants to scrutinize the function and impact of such capabilities. When the trend is for LIS not to simply report an achieved result, but to also provide interpretation, the line blurs and new regulatory requirements may result.

"Regulators will be a factor in the future development of LIS software," stated Spratt. "The counterbalancing force comes from instrument vendors and manufacturers. This is market driven and centers around quality standards known as ISO-9000."

Most readers of THE DARK REPORT are unfamiliar with ISO-9000. Because

ISO-9000 Standards Important To Industry

Even while managed care began transforming healthcare services in the United States during the late 1980s and early 1990s, the business world was undergoing its own revolution.

Inspired by Japanese success with robust manufacturing techniques, companies were learning how to create manufacturing systems that, by definition, could only fabricate products correctly. They were learning how to function with zero inventories, using Just-In-Time (JIT) techniques.

There was just one problem. If a company was working with zero inventories, how could they rely on a supplier to ship them parts which were free of defects and guaranteed to work properly? Any defective parts sent by a supplier would shut down a plant operating on zero inventories.

The answer was ISO-9000. These are standards administered by the **International Standards Organization**, based in Europe. When a company is certified to be in compliance with IS0-9000 standards, its products are acceptable to manufacturers throughout the world. Ideally, any ISO-9000 company can be trusted to deliver products of specified quality.

ISO-9000 certification is time-consuming and expensive. A small manufacturer may spend up to two years and $250,000 becoming certified. But that certification opens up worldwide markets that are closed to uncertified companies.

of international trade practices, ISO-9000 certification is becoming a requirement for manufacturers who want to sell their products throughout the world. Most large medical instrument manufacturers are already certified as meeting ISO-9000 standards. They will be introducing these management practices into clinical laboratories and other healthcare providers.

Spratt explained why ISO-9000 will influence LIS software. "We recognize that certified good manufacturing procedures, such as those described in ISO-9000, will be necessary preconditions to LIS software development to support each emerging generation of medical instruments, equipment and computers."

Inevitable Convergence

"The inevitable convergence of medical software and medical devices into an interoperable, highly partitioned network dictates regulatory compliance at every level and with every component."

Having described the dual trends of clinical information integration and process controls, Spratt predicted three basic differences between existing LIS software and the coming versions.

"First, there will be big changes to the product itself," he said. "The interface engine of the LIS will become more sophisticated. It will permit an unparalleled degree of interaction between testing instruments, the data base repository and users of clinical data.

"Second, coming generations of LIS software will be partitionable. The software itself will follow point-of-care testing and near-patient testing to any site within the 'virtual' laboratory. It will achieve this through effective use of software components, or 'applets.' These are small application

modules similar to the Java programs now used on the Internet.

"Third, LIS software will be organized to support quality management programs. It will permit management to reengineer laboratory processes on a continuous basis. It will support productivity improvement and cost-cutting initiatives. In this role, LIS will become an essential management tool."

Spratt's prediction that LIS will become an important management tool is probably his most significant. It means that successful laboratories must do two things. First, they must identify and acquire a truly effective laboratory information system. If the LIS is not effective, the laboratory's ability to compete will be crippled.

Second, laboratory executives will need to develop knowledge and skill to use LIS as a management tool. Without such knowledge, the capabilities of the LIS to deliver lower costs, improved quality and enhanced service will remain untapped. Again, the laboratory will find itself to be at a competitive disadvantage.

Spratt articulates a precise vision of how coming generations of LIS software must support clinical laboratories. He acknowledges that the LIS industry still has many serious challenges to achieve future success. One area is software implementation.

"Anytime a clinical laboratory upgrades software or converts to a new software product, the cost of the conversion process equals or exceeds the cost of the software itself. Our goal is to develop an LIS software product which is easy to install, doesn't create major disruptions, and where installation costs are significantly smaller than the cost of the software itself."

Spratt correctly identifies the Achille's heel of laboratory information system vendors. No company has a software product which is user friendly, meets customer expectations in all types of laboratory settings and is easy to install and operate. Any company which successfully designs such a product would dominate the market for LIS.

Because an LIS conversion or upgrade is probably the most painful activity that a laboratory can undergo, most knowledgeable observers are skeptical that such an LIS software product will hit the marketplace in the near future.

New Insights

What is important about Spratt's predictions is that laboratory executives have new insights to consider as they ponder whether to upgrade existing LIS or move to a new system. If just a small portion of what Spratt foresees were to become reality, the importance of LIS to laboratory success will increase.

This makes it critical that laboratory executives give LIS decisions greater attention than in the past. Wise decisions will bring competitive advantage. **TDR**

(For further information, contact Randall Spratt at 541-485-2338.)

South Bend Med Foundation Installs Laboratory Automation

When Indiana's largest laboratory completed installation of its automated laboratory project, it became the first operating site for ***Boehringer Mannheim Corporation's*** *automation product.*

The system was installed last fall and became operational early this year. It is expected to be Boehringer's "showcase" in the company's efforts to sell additional installations.

South Bend Medical Center's *laboratory uses Boehringer's system in the areas of chemistry, hematology, coagulation, immunochemistry and urinalysis testing.*

Questions, Answers & Viewpoints

Dear Editor:
The story in your February 17 issue about laboratory automation as viewed by an industrial engineer was fascinating. He did a great job of helping me understand how to look at clinical laboratory automation. However, you say nothing about the centralized/decentralized issue. Isn't automation predicated on the concept of a centralized laboratory with a high volume of specimens? What happens if this "virtual laboratory" I read about actually does diffuse testing throughout my hospital system, ending the centralized laboratory as it exists today? What then happens to my investment in automated lab systems?
P.S.,MD, NY, NY

Answer:

You realize the dilemma most laboratory directors face today. In the pursuit of lower costs, laboratory automation offers the promise of considerable savings. That requires answers to two questions.

First, can the proposed laboratory automation project pay for itself in a reasonable time period? Mark Smythe, the industrial engineer who authored that article on laboratory automation, says he generally wants a project's return on investment to be 12 months or less.

He reasons that unexpected expenses always increase the cost of the project while extending the implementation time. He also has many alternative cost-saving opportunities and he doesn't want to spend large sums of money that cannot be recovered in a short time period.

Second, if the "virtual laboratory" does begin appearing in the next 24-36 months, what does that do to your existing laboratory configuration, particularly if you have already invested heavily in automation?

Remember, even as automation vendors design equipment for lab locations with relatively high specimen volumes, competing instrument manufacturers are working equally hard to create miniaturized test instruments best suited to "point-of-care" or "near-patient" settings. Also, vendors are developing modular instrument systems which include self-contained automation.

Your answers to these two questions will drive your automation decision. If you determine that automation provides an acceptable payback for your laboratory and if your strategic outlook indicates your hospital system will be best served by point-of-care/near-patient testing capability, then you may want to defer any huge investment in laboratory automation.

Also, don't overlook how the structure of laboratory organizations, and the technology which they incorporate, represent moving targets. Whatever information you base your decision upon will become outdated in six months to a year. It is necessary for you to regularly revisit your assumptions as you plan your options.

--Editor

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

After THE DARK REPORT'S *Executive War College on Medical Laboratory Networking* in New Orleans on May 20-21, two other interesting laboratory meetings are scheduled. First up is the 15th annual symposium presented by the **University of Michigan's** Department of Pathology. Scheduled for May 28-30 in Ann Arbor, Michigan, it is titled "Automated Information Management In The Clinical Laboratory." It is the biggest meeting of the year which focuses entirely on laboratory information systems and related topics. On June 18-20, **ARUP Laboratories** and the **University of Utah** School of Medicine will present a program entitled "Update In Laboratory Medicine And Management." Presentations are structured to address two themes: science in the laboratory and business management in the laboratory.

Provocative changes are taking place in the world of automated cytology. Even as pathologists and cytologists debate the merits of automated cytology systems, such products continue to make inroads. The latest news is that **NeoPath, Inc.** of Redmond, Washington gained approval on March 19, 1997 from the **Ministry of Health and Welfare** to sell its AutoPap System® as a primary screener in Japan.

MORE ON...NEOPATH

This is a major development. Japan is the first nation to approve an automated cytology system for primary screening of Pap smears. **Nikon Corp.** is NeoPath's distributor in Japan. Nikon handles regulatory issues and provides local support. It appears that NeoPath's choice of Nikon was a wise strategic decision. Besides the credibility that comes with Japan's decision, the 12 million Pap smears screened annually in that nation represents a lucrative market for NeoPath.

When **SmithKline Beecham Clinical Laboratories** (SBCL) sold its dialysis testing business last fall to **Bio-Reference Laboratories** of Elmwood Park, New Jersey, it didn't take Bio-Reference Labs long to decide that the purchase was not "as represented." Bio-Reference sued SBCL in December, claiming "breach of contract, misrepresentation and fraud" relating to the sale of assets. The lawsuit alleges that SBCL fraudulently concealed the nature and extent of the federal investigation which resulted in SBCL's $325 million federal settlement in February. This negatively affected the dialysis accounts and revenues SBCL sold to Bio-Reference.

BACK IN THE LAB BUSINESS

After several year's absence, former **Damon** executive Tom Liccardi has returned to the laboratory industry. He recently assumed duties as Director of Sales and Marketing at **Physicians Clinical Laboratories** in Sacramento, California.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 21, 1997

THE DARK REPORT

UPCOMING...

- *Rural Hospital Laboratory Develops Thriving Outreach Business.*
- *Regulatory Initiatives Intended To Erode Laboratory Reimbursement.*
- *Update On The Regional Laboratory Network Movement.*
- *Laboratory Management Strategies That Cut Costs And Improve Quality.*