Volume XI, Number 15 Monday, November 1, 2004

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

R. Lewis Dark:
Facing Down the Lab Assay Patent Monster..... Page 1

Homocysteine Test Patent
Triggers Royalty Payment Demand..... Page 2

British Columbia Labs' LOINC Venture
Now Carries Pharmacy Info..... Page 5

Lab Compliance Update: Physician Group Pathology
Ventures to Undergo OIG Review in 2005..... Page 7

PART THREE OF A SERIES:
Aligning Pathologist Productivity
With Compensation Can Be Challenging..... Page 9

Lab Briefs: Applied Digital's Verichip™,
Laboratory Corp. of America..... Page 17

Intelligence: Late-Breaking Lab News..... Page 18

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Facing Down the Lab Assay Patent Monster

PATENT ROYALTIES FOR HOMOCYSTEINE TESTING are the subject of our lead story in this issue. *(See pages 2-4.)* It provides an early example of how patent-protected diagnostic tests can create budget-busting problems for hospital laboratories which perform those tests.

The spectre of crushing royalty payments on a host of patent-protected diagnostic assays has loomed large over the strategic planning activities of the nation's hospital laboratories. That spectre is fast becoming a reality. In recent months, hundreds of hospital laboratories recieved royalty demand letters from **Competitive Technologies, Inc.** (CTI). These letters ask for royalty payments to be made on all homocysteine tests performed as far back as January 1, 1998. CTI estimates that 20 million homocysteine tests will be performed this year, so the impact of royalties on these tests can be substantial for labs doing high volumes of homocysteine testing.

CTI has made efforts over the years to collect royalties from labs on homocysteine testing. But that effort intensified this summer. That's when CTI prevailed in its lawsuit against **Laboratory Corporation of America**. CTI alleged several torts, including violations of a contract and infringing the homocysteine patent. The federal court ruled in CTI's favor, and the judgement was upheld on appeal. LabCorp paid the judgement to CTI in August.

Emboldened by this court success, CTI sent another round of demand letters to hospital laboratories and independent laboratories it believes are doing homocysteine testing covered by its patent. Since the demand letter asks for royalties on tests performed since 1998, the total royalty amount for any affected laboratory could be significant, relative to its current budget.

Setting aside the validity of CTI's patent claims on homocysteine testing, its current royalty-demand campaign puts the issue of patents on diagnostic tests front and center. As clients and regular readers of THE DARK REPORT know, literally hundreds of biotech companies are researching molecular markers for therapeutic drugs and diagnostic assays. Patent protection of their discovery is the end goal. At some future point, the laboratory industry will have to square off with the patent/royalty monster. It remains to be seen whether the monster can be tamed, or whether it will wreak havoc on the financial condition of the nation's laboratories. TDR

Homocysteine Patent Triggers Royalty Demand

Hospital labs getting demand letter from patent holder to pay royalties

CEO SUMMARY: Laboratory Corporation of America fought a patent infringement case against the holder of the homocysteine assay patent and lost after a five-year court battle. Now Competitive Technologies, Inc. (CTI), armed with its victory in federal court, is ready to negotiate royalty arrangements with laboratories, IVD manufacturers, and even physicians. Labs all over the United States are getting demand letters from CTI.

HUNDREDS OF HOSPITAL LABS and other labs throughout the United States are currently receiving a letter from **Competitive Technologies, Inc.** (CTI) which demands that royalties be paid for homocysteine tests performed as far back as 1998.

Any laboratory which performs homocysteine testing can expect to find itself facing a demand by Competitive Technologies. Although CTI had sent royalty demand letters to selected laboratories in recent years, it intensified its collection efforts during the past six weeks. That is why greater numbers of laboratories received demand letters in recent weeks.

CTI believes it has a strong legal club to use in enforcing its patent rights. Earlier this summer Competitive Technologies prevailed over **Laboratory Corporation of America** in a federal court case that took five years to conclude. Lower courts ruled in favor of CTI and licensee **Metabolite Laboratories**, finding that LabCorp infringed CTI's homocysteine assay patents. A federal appeals court upheld the verdict of the lower courts and ruled against LabCorp.

The district court assessed damages of $3.6 million for breach of contract and $1 million for indirect infringement. The district court further granted the motion by CTI and Metabolite "to enjoin LabCorp from performing 'any homocysteine-only test, including without limitation homocysteine-only tests via the **Abbott [Laboratories]** method'."

Under a court-directed agreement dated December 2002, LabCorp has

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.55 per week elsewhere (billed semi-annually).

paid a 6% royalty to CTI and its clients on current homocysteine testing performed in its labs and covered under CTI's patent rights. With the conclusion of this federal court case, Competitive Technologies is expanding its royal collection efforts.

Enforcing Its Patent

"In addition to LabCorp, we are pursuing licensing discussions and collection of royalties from other companies involved with homocysteine testing. The largest companies in the marketplace include Abbott Laboratories, **Bayer AG** and **Axis Shield PLC**," stated John B. Nano, President and CEO of CTI. "We expect to reach licensing agreements with several organizations in lieu of formal dispute."

CTI wants to calculate royalties based on a formula that is 6% of the "patient's cost, before insurance reimbursement." It is targeting homocysteine tests performed from January 1, 1998 through the present. In the demand letter received by one laboratory (reproduced in the sidebar on the facing page), it requests a $30,000 licensing fee and royalties "payable at the rate of $1.83 per test sold." It also requests a "full accounting of all past homocysteine tests retroactive to January 1, 1998."

Homocysteine Royalties

The royalty potential of the homocysteine patent assay is substantial. CTI estimates that 20 million homocysteine assays will be performed in 2004. It believes the successful outcome of its patent infringement case with LabCorp in federal court gives it a legal precedent which bolsters its efforts to protect its homocysteine assay patent.

Royalty payments for patent-protected diagnostic assays is an emotional issue for pathologists and laboratory scientists, as is the increase in the number of high-priced proprietary esoteric tests. For hospital laboratories, which generally operate in support of a not-for-profit hospital or integrated health system, the extra expenses generated by these types of tests are feared as "budget-busters."

The sudden demand by CTI to cough up royalty payments for homocysteine tests done over the past six years justifies these concerns. Most hospital labs have no financial reserve available to fund such payments.

Competitive Technologies holds the assay patent on behalf of the **University of Colorado** (developers Robert H. Allen, M.D. and Sally Stabler, M.D.) and **Columbia University** (developer John Lindenbaum, M.D.–died 1997.)

Patent Claims for '658

U.S. Patent NO. 4,940,658 (the '658 patent) "claims methods for detecting cobalamin or folate deficiencies in warm-blooded animals." It was developed in research to benefit patients with sickle cell anemia and vitamin B-12 deficiency, among other diseases. The patent claim covers the process of determining cobalamin and/or folate deficiency, based on a correlation with elevated levels of homocysteine.

In the 1990s, clinical studies began to uncover a relationship between high levels of homocysteine and increased risk of heart disease. Based on these findings, clinicians began ordering higher volumes of homocysteine tests to use in evaluating a patient's risk of heart disease. It was the determination of the federal court in the CTI/Metabolite vs. LabCorp case that the "new use" for homocysteine testing was still covered by the '658 patent claim. Thus the ruling that LabCorp infringed the patent.

The arrival of royalty payment demand letters at laboratories throughout the United States triggers a new management challenge. Most labora-

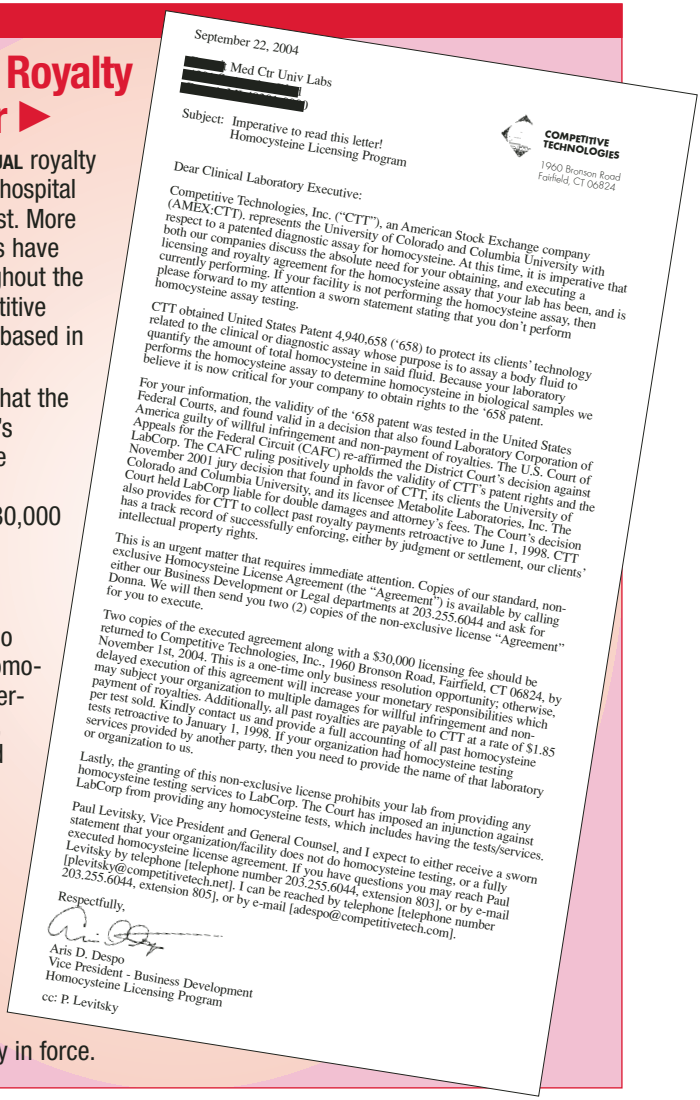
Homocysteine Royalty Demand Letter ▶

HERE IS A COPY OF AN ACTUAL royalty demand letter sent to a hospital laboratory in the Midwest. More than 700 of these letters have been sent to labs throughout the United States by Competitive Technologies, Inc. (CTI), based in Fairfield, Connecticut.

The letter requests that the laboratory complete CTI's "standard, non-exclusive Homocysteine Licensing Agreement," attach a $30,000 licensing fee, and return these items to CTI by November 1, 2004.

The laboratory is also requested to audit all homocysteine testing it has performed since January 1, 1998 and kindly forward along a full account of same.

Finally, the letter notes that the non-exclusive license prohibits the lab from "providing any homocysteine testing services to LabCorp," per the court injunction currently in force.



September 22, 2004

[redacted] Med Ctr Univ Labs

[redacted]

Subject: Imperative to read this letter!
Homocysteine Licensing Program

COMPETITIVE TECHNOLOGIES
1960 Bronson Road
Fairfield, CT 06824

Dear Clinical Laboratory Executive:

Competitive Technologies, Inc. ("CTT"), an American Stock Exchange company (AMEX:CTT), represents the University of Colorado and Columbia University with respect to a patented diagnostic assay for homocysteine. At this time, it is imperative that both our companies discuss the absolute need for your obtaining, and executing a licensing and royalty agreement for the homocysteine assay that your lab has been, and is currently performing. If your facility is not performing the homocysteine assay, then please forward to my attention a sworn statement stating that you don't perform homocysteine assay testing.

CTT obtained United States Patent 4,940,658 ('658) to protect its clients' technology related to the clinical or diagnostic assay whose purpose is to assay a body fluid to quantify the amount of total homocysteine in said fluid. Because your laboratory performs the homocysteine assay to determine homocysteine in biological samples we believe it is now critical for your company to obtain rights to the '658 patent.

For your information, the validity of the '658 patent was tested in the United States Federal Courts, and found valid in a decision that also found Laboratory Corporation of America guilty of willful infringement and non-payment of royalties. The U.S. Court of Appeals for the Federal Circuit (CAFC) re-affirmed the District Court's decision against LabCorp. The CAFC ruling positively upholds the validity of CTT's patent rights and the November 2001 jury decision that found in favor of CTT, its clients the University of Colorado and Columbia University, and its licensee Metabolite Laboratories, Inc. The Court held LabCorp liable for double damages and attorney's fees. The Court's decision also provides for CTT to collect past royalty payments retroactive to June 1, 1998. CTT has a track record of successfully enforcing, either by judgment or settlement, our clients' intellectual property rights.

This is an urgent matter that requires immediate attention. Copies of our standard, non-exclusive Homocysteine License Agreement (the "Agreement") is available by calling either our Business Development or Legal departments at 203.255.6044 and ask for Donna. We will then send you two (2) copies of the non-exclusive license "Agreement" for you to execute.

Two copies of the executed agreement along with a $30,000 licensing fee should be returned to Competitive Technologies, Inc., 1960 Bronson Road, Fairfield, CT 06824, by November 1st, 2004. This is a one-time only business resolution opportunity; otherwise, delayed execution of this agreement will increase your monetary responsibilities which may subject your organization to multiple damages for willful infringement and non-payment of royalties. Additionally, all past royalties are payable to CTT at a rate of $1.85 per test sold. Kindly contact us and provide a full accounting of all past homocysteine tests retroactive to January 1, 1998. If your organization had homocysteine testing services provided by another party, then you need to provide the name of that laboratory or organization to us.

Lastly, the granting of this non-exclusive license prohibits your lab from providing any homocysteine testing services to LabCorp. The Court has imposed an injunction against LabCorp from providing any homocysteine tests, which includes having the tests/services.

Paul Levitsky, Vice President and General Counsel, and I expect to either receive a sworn statement that your organization/facility does not do homocysteine testing, or a fully executed homocysteine license agreement. If you have questions you may reach Paul Levitsky by telephone [telephone number 203.255.6044, extension 803], or by e-mail [plevitsky@competitivetech.net]. I can be reached by telephone [telephone number 203.255.6044, extension 805], or by e-mail [adespo@competitivetech.com].

Respectfully,

Aris D. Despo
Vice President - Business Development
Homocysteine Licensing Program

cc: P. Levitsky

tories probably lack a policy on this type of legal issue. Those that have a policy may find it lacks the detail and depth needed to provide effective guidance in this case.

Letters To 700 Labs

Competitive Technologies says that it has sent out more than 700 royalty demand letters to laboratories. That means the issue of paying royalties on homocysteine assays is one which must be addressed and cannot be side-stepped.

Further, this must be considered an early example of the trend which has been much-discussed, but little seen until now: the growing number of patent-protected diagnostic assays for which a royalty fee is included in the cost of each test performed. What remains unknown is how the healthcare system will pay for this added cost. Payers have not yet been required to deal with this issue on a large scale. **TDR**

Contact John B. Nano at 203-255-6044.

BC Labs' LOINC Venture Now Carries Pharma Info

PathNET is becoming a Web portal for a variety of healthcare services

***CEO SUMMARY:** In British Columbia, two commercial laboratory companies are intense competitors. Yet, beginning in 2002, they jointly offered a single Web browser-based system for lab test results reporting. LOINC was the tool which linked their individual lab data repositories to the PathNET portal. Now the provincial health ministry has authorized the use of PathNET to allow physicians to access its patient drug history data base.*

By June Smart, Ph.D.

In British Columbia, the province-wide laboratory test results reporting system, called **PathNET**, now includes pharmaceutical data.

This is a significant milestone for PathNET, which is a Web-browser based system that allows physicians throughout British Columbia to access lab test reports. PathNET is unusual because of one fact: its owners are two competing commercial laboratory companies.

Competing Labs Collaborate

BC Biomedical Laboratories and **MDS Metro Laboratory Services** formed PathNet in 2000. Its original goal was to be a value-added service to office-based physicians in the province. Between them, the two lab companies perform 70% of the outpatient tests ordered by physicians in British Columbia. PathNET uses LOINC® (Logical Observation Identifiers Names and Codes) to combine lab test result data produced by each laboratory. *(See TDR, August 26, 2002.)*

"Adding pharmaceutical data to PathNET is a major step forward for integrated information services in British Columbia," stated Tom Cooney, M.D., President of PathNET. "Physicians will now be able to click on the PathNET icon, obtain the test results for their patient, then go directly into the Pharmanet data base and obtain that patient's drug history.

"Prior to this new arrangement, the pharmaceutical data base was housed at the **British Columbia Ministry of Health** (BCMH)," he explained. "It provided patients' drug histories to emergency rooms and pharmacies and, in a pilot program, up to 100 office-based physicians. The interface between PathNET and BCMH's Pharmanet expands the number of physicians who can access patient drug histories to 3,400!"

"This will be an incredible time saver and will contribute significantly to improved patient care," observed Cooney. "Patient privacy protections are built into the drug history data base and all compliance issues have been addressed."

Pharmanet service will be available to physicians at no charge. Discussions are in progress between PathNET and the Ministry of Health regarding the incremental costs of educating physicians about the feature and how to access it through PathNET.

Lab IT Is Access Point

"Enabling access to the patient drug history data base through the PathNET Web portal validates a major business assumption we made when BC Biomedical and MDS Metro initially created this information services joint venture," said Cooney. "We saw the need to develop integrated access to clinical data and patient information. Healthcare is moving toward a fully-digital information system. We believed it essential that laboratories play a leading role in integrating and digitizing laboratory test data.

"PathNET has been a solid success in British Columbia. When it launched in early 2001, it served office-based physicians. Since then, four major hospitals have linked emergency rooms and pre-admission clinics to PathNET. The interface with Pharmanet was another major enhancement," explained Cooney.

Two Other Developments

"Even as I am speaking with you, there is progress on two other important developments which will use PathNET as a major IT access point for healthcare providers," he continued. "For example, we are moving forward with the **Native Investment and Trade Association** (NITA), a national Aboriginal group, to enable PathNET services to go nationwide in Canada in the creation of an electronic medical summary for First Nations people.

"Another initiative involves patient scheduling," Cooney said. "A physician developed a data base to automate specialist physician availability for appointments. There is a pilot program under way to determine if PathNET is the right vehicle for delivering this service to the physicians. Early indications are that physicians are most receptive to this additional service."

PathNET's growth and progress since its launch in 2001 validates predictions made by THE DARK REPORT at that time. We believed that BC Biomedical Labs and MDS Metro Labs—two companies which compete intensely against each other—were taking few risks in creating an effective Web browser-based system to allow physicians to view lab tests. The order entry module, allowing physicians to order lab tests from the office is in the final development phase.

Using LOINC To Advantage

Our prediction was that PathNET, once it was in operation, was likely to become an access point for other clinical information and services. Because it was using LOINC as the tool to combine information flows from each lab's test data repository, that would make it easy for other laboratories in the province to make their lab test services available through PathNET. **Valley Medical Laboratory**, another major community lab in BC, now uses the system and its lab test data is part of the integrated database.

Further, THE DARK REPORT has always believed that regional collaboration between laboratories, whether or not they are competitors, has the potential to create a critical mass which, in itself, adds value to clinicians, payers, and patients. What is notable in British Columbia is how two commercial lab ventures have succeeded in this dimension of their regional collaboration.

Will PathNET play a major role in helping develop whatever final form of universal patient medical record format is developed in British Columbia? That is an intriguing possibility. TDR

Contact Tom Cooney, M.D. at tcooney@pathnet.ca.

Lab Compliance Update

Physician Group Path Ventures To Undergo OIG Review in 2005

IN ITS FISCAL YEAR 2005 WORK PLAN, the **Department of Health and Human Services** (DHHS) **Office of Inspector General** (OIG) will "identify and review relationships between physicians who furnish pathology services in their offices and outside pathology companies."

It is another sign that federal healthcare investigators are concerned that more specialist physician groups are creating some type of business arrangement designed to capture the revenues from anatomic pathology (AP) services performed from their patient referrals. Earlier this year, the OIG made an unusual public statement, declaring that such arrangements pose significant kickback risks and can lead to excessive referrals.

"The OIG's stated interest in this topic is a significant event," observed Jane Pine Wood, Attorney and Principal at **McDonald Hopkins**, the law firm based in Cleveland, Ohio. "The OIG's willingness to spend time and resources to study this trend is a sign that it sees problems with what is happening in the healthcare marketplace."

OIG's Choice Of Words

Wood considers the specific wording used in the OIG's work plan description to be revealing. "Take the first sentence, which reads 'Our review will focus on pathology services performed in physicians' offices.' The specific emphasis on 'pathology services in *physicians' offices* {my italics} is a key distinction," she noted. "It links to a deliberate choice of words in the second sentence, which says 'examination of cells or tissue samples by a *physician who prepares a report of his findings*' {my italics}. I believe this indicates three areas of OIG concern.

"One, the emphasis is not on a pathology laboratory or a pathology group practice. The OIG study will look at non-pathology medical group practices that are, in some form or another, directly involved in performing AP services on their own patients," observed Wood.

Interpreting AP Cases

"Two, I believe the OIG study intends to look at which physicians are interpreting AP cases," she said. "The OIG might be concerned, for example, that a pathologist who is not appropriately licensed is interpreting these cases. I've been told of situations where, say, a urology group owns an AP condominium lab in another state. The case is read by a pathologist in the state where the laboratory is located, but the pathologist is not licensed in the state where the urology practice and the patient are located (which often is required under state medical practice statutes).

"Furthermore, to avoid license restrictions or for managed care contracting reasons, a urologist in the group practice may actually sign the pathology report in order to bill for the professional component. That type of arrangement raises several relevant issues of medical ethics and regulatory compliance," added Wood.

"Three, it is obvious that concerns about unnecessary utilization underlie this OIG study," continued Wood. "The sentence which follows the first two states 'Medicare pays over $1 billion annually *to physicians* {my italics} for pathology services.'

"I believe the choice of the word 'physician' over 'pathologist' is deliberate. It seems the OIG is concerned about situations where physician groups have an arrangement that allows them to bill for anatomic pathology services provided to their patients. This is a self-referral arrangement and has many direct parallels with all the self-referral, inducement, and kickback issues involving clinical laboratories and their referring physician-clients that have incited OIG enforcement action over the past 15 years.

"Further, if my interpretations of the OIG work study statement are accurate, they dovetail neatly with what is happening in the private payer community," explained Wood. "There are numerous examples of payers reviewing the provision of ancillary services by physician practices. Whether radiology, pathology, or similar ancillaries, payers are reacting to the trend of physician groups actively establishing arrangements that allow them to bill for ancillary services performed on behalf of their groups' patients.

Outside Path Companies

"Finally, a comment on the OIG's final sentence, the one that reads 'We will identify and review the *relationships between physicians who furnish pathology services in their offices and outside pathology companies*.' [my italics]. What companies is the OIG referencing if not the anatomic pathology condominium complex operators which have caused such a fuss lately?" asked Wood. *(See TDRs, July 19 and August 9, 2004.)*

"For pathology group practices—and for individual pathologists interested in contracting services to a physician group practice—the OIG's statement is a warning flag," she added. "Like many other attorneys, I have advised great caution whenever a physician group wants to craft a business relationship that allows it to financially benefit from the anatomic pathology services provided to its patient population. In the foreseeable future, these types of arrangements may come under detailed scrutiny by both private payers and government health program investigators. Compliance with all applicable federal and state laws is critical."

The OIG's 2005 Work Plan should be viewed in context with two other dynamics involving clinical lab and anatomic pathology services. The first is proposed Medicare regulations that will tighten the definition of "usual and customary charges." That is a direct attack on "client bill" or "discounted billing" arrangements between a lab and a physician client.

The second is the criminal indictments in the **UroCor** case. One section of the indictment alleges that UroCor paid a kickback to urologist-clients when it offered discounted, below-cost prices to the urologist, who then billed private payers for the "usual and customary charge" and pocketed the difference. With a court trial yet to commence, it would seem an inauspicious time for any pathologist to enter into any business arrangement that somehow splits technical and professional fees with a referring physician. TDR

Contact Jane Pine Wood at 508-385-5227.

OIG's 2005 Work Plan

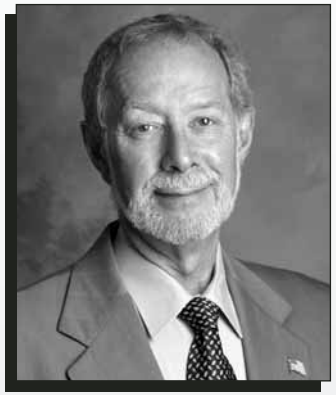
IN PUBLISHING ITS 2005 WORK PLAN, the Department of Health and Human Services (DHHS) Office of the Inspector General (OIG) specifically identifies a project to study aspects of how pathology services are performed within physician group practices. The short paragraph in the work plan which describes the project is reproduced below:

Physician Pathology Services

Our review will focus on pathology services performed in physicians' offices. Pathology services include the examination of cells or tissue samples by a physician who prepares a report of his findings. Medicare pays over $1 billion annually to physicians for pathology services. We will identify and review the relationships between physicians who furnish pathology services in their offices and outside pathology companies.

(OAS; W-00-05-35164; various reviews; expected issue date; FY 2005; new start)

NEWSMAKER INTERVIEW



Aligning Pathologist Productivity With Compensation Is No Easy Task

"Growing interest in ways to link a pathologist's productivity to his/her compensation makes this a widely-discussed topic within many pathology group practices."
–Dennis Padget

CEO SUMMARY: Part Three continues THE DARK REPORT'S series on measuring pathologist productivity. In this installment, pathology practice consultant Dennis Padget identifies different approaches to appropriately link pathologist productivity with compensation. After four decades of service to the pathology profession, Padget, of Simpsonville, Kentucky-based **DLPadget Enterprises, Inc.**, recently retired. This interview was conducted by THE DARK REPORT'S Editor-In-Chief, Robert L. Michel

PART THREE OF A SERIES

EDITOR: Let's resume our earlier discussion of workload-based performance compensation systems for pathologists. *(See TDR, October 11, 2004.)* Before plunging into this topic, would you review for our readers the most prevalent compensation models in use today, regardless of their basis. That would give us context about the role that performance-based systems can play. What is the most prevalent compensation model and which is the least prevalent?

PADGET: Thanks for inviting me back. I must preface my remarks by stating that I'm not a physician compensation and benefits consultant. These were not areas in which I focused my attention when working with pathology clients in the past. So the sense of proportion I'll give you is from my gut, not from reliable study. I could be way off on the numbers, but my description of the various models will be on target.

EDITOR: Understood.

PADGET: My sense is that, by far, the most prevalent compensation model used by pathology groups today is highly democratic: The group simply divides total income equally among all its shareholders or partners. During the year, all pathologists get the same base salary. Whatever undistributed income remains at year's end is divided equally as a bonus.

EDITOR: What compensation model would come next in frequency of use?

PADGET: Likely the next most common model starts with a staggered base salary. Essentially, the most senior members of the group have a materially higher base salary than the junior members. Any undistributed group income left over at year's end is given out as a bonus. The bonus might be distributed equally among all the shareholders or partners. Alternatively, it might be distributed based on some weighting factor, like base salary.

EDITOR: What compensation model is least often seen in pathology?

PADGET: Workload performance, sometimes referred to as the "eat-what-you-kill" approach. In my experience, this is the least-used compensation model. Some independent laboratories operate from this approach, but it is seldom used by hospital-based pathology group practices.

EDITOR: Can you speculate as to why the fundamental models you've described might be encountered in the proportion you cite? For example, why might the equal distribution model be the most prevalent?

PADGET: There seems to be a strong correlation between practice size and the compensation model used by a particular group. The equal distribution method fits well with small- to medium-size hospital-based practices. In this environment, all the pathologists tend to do a little of everything. That makes it relatively easy to divvy up the work equally. Patient cases, marketing, practice administration, lab oversight, and similar tasks are evenly shared among all pathologists in the group. So it makes sense that total practice income is shared equally as well.

EDITOR: I recall reading somewhere that small- to medium-sized groups dominate the pathology profession. If they are the ones most likely to use the equal distribution model, it stands to reason it would dominate too.

PADGET: Right. According to a survey by the **College of American Pathologists** (CAP) in 2002, 57% of respondents practiced in a group of one to six members. Further, 74% belonged to a group of one to ten members.

EDITOR: What type of setting encourages the compensation model based upon varying salaries for senior and junior pathologists?

PADGET: The "salary range" model is often used by large hospital-based practices. When you think about the usual characteristics of such a practice, this correlation makes sense as well. There is typically a

wide range in the age and years of practice of the members. Many years separate the most senior from the most junior member. Skill and degree of subspecialization vary significantly. There is often a pronounced difference between pathologists in preference for work versus leisure. These, and other factors, can readily be accommodated by a salary range compensation system, to the point that most everyone in the group agrees the outcome is fair and reasonable.

EDITOR: That's interesting. What are your thoughts about the pure workload compensation model?

PADGET: In my opinion, the pure workload performance compensation model is ideally suited for the independent lab environment. In this setting, pathologists are focused on reading slides and churning out reports, almost to the exclusion of everything else. They don't get many frozen sections, and "curbside" consults with surgeons are rare. They are seldom saddled with administrative duties, and because of specialization, they are less likely to be looking at tissue one minute, a Pap smear the next, and a peripheral blood smear the third. Compared to the inpatient hospital setting, there's not a huge variation in case complexity.

EDITOR: So the work is focused and fairly homogenous, which makes it like an assembly line. Those are factors commonly felt to be necessary to make a workload performance compensation system function well in the manufacturing and other business sectors. Is that what makes it apropos for use by independent laboratories?

PADGET: Yes, you've got it just right! Pathologists want to get their work done early in the day, and then leave. Moreover, the lab corporation has a legitimate business need to incite high productivity. Thus, paying pathologists on a piecework basis in this type of laboratory setting makes eminent sense.

EDITOR: That brings us to an interesting contradiction. The majority of pathology groups are not using performance-based compensation systems to pay their physicians. Yet there's plenty of talk in the profession about the benefits of linking productivity to income distribution. How do you explain this apparent contradiction?

PADGET: Workload performance compensation is a sexy concept! But its promise is likely overrated. This compensation approach is not right for every pathology group. I'll explain, first from the perspective of the academic pathology environment, and then from the private practice environment.

EDITOR: Okay.

PADGET: If I were the chair of an academic medical center pathology group, I'd be very skeptical of trying to use productivity directly in my faculty compensation formula. The system would have to be very, very complex, because the faculty duties are so diverse.

EDITOR: That's true.

PADGET: For example, what common denominator is there that equates the work of a transfusion medicine physician with that of a neuropathologist, or the head of the autopsy service, or the physician director of microbiology? Even if you could devise such a linkage, would the incentive encourage the response you want, or something quite different? Look at it this way: You install a system that pays your surgical pathologists on a piecework basis to stimulate productivity; but what then happens to resident education? Will the quality and quantity of training diminish as attentions become focused on the compensation "carrot" you've put out there?

EDITOR: Academic pathology departments also have a different mission and budget process. That influences the options for crafting a feasible package of total pathologist compensation.

PADGET: True. There are faculty incentive compensation programs that work well in an academic environment, but I don't think pure workload performance is one of them. A program that uses negotiated individual goals is an example. The chair sets aside a pool of dollars to fund faculty bonuses for the coming year, and then meets with each member of the faculty to mutually agree on a set of individual goals. Each member's bonus is linked to those goals and is paid in proportion to attainment.

EDITOR: But the goals have to be objective and measurable. And some could be workload-based. Correct?


Dennis Padget

Every pathology group must carefully weigh the pros and cons before plunging into an arrangement where compensation is heavily linked to each pathologist's personal productivity.

PADGET: Yes. Workload-oriented items might well be included, but those goals will be tailored to each individual's responsibilities. It helps the chair better control for unintended consequences this way. This type of compensation approach provides many of the advantages of an incentive system, but without all the risks of the pure productivity model.

EDITOR: Good. Let's turn to the private practice environment for a moment. The big difference here is not having to worry about resident education. So private practitioners have more to gain and fewer risks with pay-for-performance, right?

PADGET: The critical question for private practice groups to ask is "what is gained if each pathologist's compensation is based on his/her personal productivity?" Like everything else, there's a cost to developing, installing and maintaining the incentive system. There is also the risk it won't work as expected—that it will have a negative outcome, not a positive one. Every pathology group must carefully weigh the pros and cons before plunging into an arrangement where compensation is heavily linked to each pathologist's personal productivity.

EDITOR: That's sound advice. People don't always remember there is a cost to craft a compensation system that functions smoothly. But you are also saying there's nothing inherently superior about a pay-for-performance arrangement, compared to something like the equal income distribution model.

PADGET: Think about a small- to medium-sized group practicing at a community hospital. It's close-knit. Everybody likes and respects everybody else. Work is evenly shared. Each pathologist pulls his or her own weight. Income is equally divided and nobody's unhappy. What does such a group have to gain by converting to a performance-based compensation system? If the truthful answer is "not a lot," then the risk of backfire clearly outweighs any change benefit. You will be better off to stay with the existing compensation arrangement.

EDITOR: You definitely have concerns about linking money to pathologist-productivity.

PADGET: It may sound like I'm "down" on performance-based compensation systems, but I'm really not. They definitely have their place. In certain situations, they have a lot to offer some groups. I simply like to emphasize the need to carefully weigh the costs, benefits, risks, and rewards before any group heads in that direction. These systems are not a surefire panacea to every problem-real or imagined. And I've seen them literally tear a group apart. It doesn't happen often, but that risk is what makes me respect their destructive powers as much as their beneficial properties.

EDITOR: Well said. But with declining payment rates for professional services, pathologist productivity is going to stay a

high profile issue for the profession. For example, younger "go getter" pathologists are mixed in with pathologists who "paid their dues" over many decades and now want to slow down. Or some groups are burdened with a pathologist who's slacked off, but still draws a full share of income. Wouldn't an "eat-what-you-kill" plan help in these situations?

PADGET: Maybe, or maybe not. And by the way, "young" no longer automatically equates to "go-getter." Today's young physicians often value leisure more than money. But back to the point. I must again emphasize that work-performance compensation isn't a panacea. There are proven ways to address these types of situations without going that route.

EDITOR: Please explain.

PADGET: For example, remember that having equal shares in a corporation doesn't mean each share holder has to be paid the same compensation. That's handled in the bylaws and the employment contracts.

EDITOR: So unequal pay for "rainmakers" and workaholics can be accommodated by using a traditional staggered salary program.

PADGET: Correct. At the other end of the spectrum, it's quite common to pay a lesser base salary to pathologist-shareholders while gradually reducing their workload in anticipation of near-term retirement. A group's accountant can assist in the details. But the message is that a group isn't forced into a work-performance compensation arrangement to cover the scenarios we've discussed. It might be a good solution, so long as the benefits look like they will outweigh the costs. But effective, reliable alternatives exist.

EDITOR: Can we come back to the problem of the under-producing pathologist? That situation seems to plague a growing number of pathology groups.

PADGET: The mention of "slackers" raises another very important point: in business as in medicine, always focus on the problem, not the symptom. The proper way to handle a pathologist who is not performing up to standard—whether in hours worked, accuracy of diagnoses, or similar—is through disciplinary action. It's definitely overkill to change a fundamental component of your infrastructure—your physician compensation system in this case—just to minimize the damage that person is causing.

Dennis Padget

In certain situations, they [performance-based compensation systems] have a lot to offer some groups. I simply like to emphasize the need to carefully weigh the costs, benefits, risks, and rewards...

EDITOR: However, most pathologists shy away from confrontation if the pathology group has a problem with one of its people.

PADGET: Maybe so, but it doesn't change the essential fact that the group has an under-producing partner, and this, not the compensation system, is the problem. I've always recommended to my clients that they address the potential of this problem at the time a new physician joins the group. Get solid legal advice to craft the group's shareholder agreement and physician employment contract so these potential issues are solved before they even happen.

EDITOR: All this background is very important, and it's been useful spending the time talking about it. But let's get down to some nitty-gritty. What development and implementation steps should a group take if it's determined that a productivity-based compensation system is the right way to go? Are there three or four critical "do's and don'ts" to more-or-less assure a successful program?

PADGET: Over my years in the profes-

sion, I've detected four keys to a successful work-based compensation system. I'll describe them in the context of the most common practice setting—the hospital. That also happens to be the setting where the biggest obstacles are encountered.

EDITOR: What's the first key?

PADGET: First, all stakeholders in the group must buy into the idea that the system will compensate fairly for work performed, but it won't necessarily distribute income in proportion to that generated by each individual physician. This is an extremely important principle that recognizes the unity and totality of the practice. It says you're not going to get 30% of the practice income just because you personally generate 30% of the revenue; some of your associates have to fulfill vital practice functions that don't generate income, or that don't generate income in proportion to the work effort.

EDITOR: All stakeholders deserve to be fairly compensated for the tasks they are asked to perform by the practice, notwithstanding the vagaries of the market and the policies of third-party payers for valuing those tasks.

PADGET: That's right. Due to CPT coding rules and insurer payment policies, major surgical resection cases typically don't yield as much income on a time-adjusted basis—like income divided by minutes—as do dermatology, GI, and urology biopsy cases. Autopsy cases may not generate any income for the group. And your hospital may not pay the practice anywhere near the value of the time that has to be spent on lab directorship and oversight duties. But the group can't just say "we won't do major surgical cases, autopsies, or Part A work anymore, because they're not very profitable." The hospital has contracted for the entire package of physician services—not just those you think are profitable—and you won't have the contract for very long if you start cutting back. So the compensation system has to pay each physician for the work units generated, not for the income that he or she personally generates.

EDITOR: Got it. What's the second key?

PADGET: Second, you have to pick a measurement unit that's fairly homogenous and reasonably reflective of work effort across a broad range of specimens and disciplines. You won't use case, because there's tremendous variability in the number of minutes required for any one case versus another. You won't use specimen, because a simple nevus will only require one or two slides, but a liver FNA or a prostate TUR may require 8-12 slides. You won't use Medicare RVU, because they involve too much "averaging. " For example, a simple nevus and a prostate TUR are both 88305 services. Another problem with RVUs is that they aren't really all that accurate from one level to the next, like minutes for an 88307 specimen versus minutes for an 88309 specimen.

EDITOR: So what would be a reasonable common denominator?

PADGET: All things considered, you'll likely select slide as the unit of measurement for your performance-based compensation system. This unit is sensible because: (1) it's common to both histology and cytology, including Pap tests; (2) even peripheral blood and body fluid smear reviews involve slides; (3) it takes add-on work, like frozen sections, immediate studies, and special stains, into account by a direct means; (4) it correlates well with case and specimen complexity; and (5) it's already captured or can easily be captured by most lab information systems. It's also relatively simple to establish an equivalency scale for hands-on procedures that aren't strictly slide-based. For example, you can assign a protein electrophoresis interpretation

an equivalent value of one or two slides, an irregular antibody reaction study a value of four to eight slides, and so on. In this way you should be able to measure basically all patient care procedures in terms of slide count.

EDITOR: That's reasonable. What's your third key to success?

PADGET: Third, you will want to establish a "slide-creep" monitoring system. You can think of this as a quality control check, much as you'd do with an automated blood chemistry analyzer; that is, you'd periodically run a check to make sure the calibration is still within acceptable tolerances. New "hands-on" clinical test interpretations will be added from time-to-time; clinical protocols will change; changes in surgical technique will alter the fundamental nature of some of the specimens you receive; and so on. Your productivity measurement system—based on slides—needs to accommodate these changes.

EDITOR: Might some people try to "game" the system? How do you check for that?

PADGET: Another major function of the "slide-creep" monitoring system is to check for unjustified patterns and trends. We'd all like to believe that nobody in our group would ever try to "game" the system, but it's better to periodically test for this than to allow an issue to fester to the point it becomes a major problem. The much more likely scenario you've got to look for and control is where one or two docs are overly cautious in their handling of certain specimens or are not following an accepted clinical protocol for some reason. Straightforward examples would be where one pathologist is unsure of himself when it comes to lymph nodes, so he orders six H&E slides per node rather than the standard two; or where group policy says you order an Alcian blue stain on esophageal biopsies only when Barrett's syndrome is suspected by the referring physician, but one pathologist routinely orders that stain "just to be sure."

EDITOR: So the objective of the monitoring system is to make certain you are not rewarding somebody for inefficient work methods or standards, however they may have come about. Is that right?

PADGET: Yes, very good! Depending on the sophistication of your lab information system, you may be able to perform this check by looking for outliers in a printout of slide count by specimen type by physician. In the worst case, you can always select a random sample of each physician's cases and look through them to see if anything unusual sticks out.

EDITOR: We're at your last key to success. What is it?

PADGET: The fourth key to a successful work-performance compensation system is also the most difficult. It focuses on all the duties and activities that, while absolutely necessary, don't directly generate billed revenue. The two biggest categories of such work are hospital lab oversight, commonly called hospital "Part A" duties, and practice administration. This consists of everything from meetings with attorneys and accountants to negotiation of hospital and managed care contracts to "beating the bushes" for more business.

EDITOR: I often hear this area is very hard to address from a productivity measurement perspective. Have you come up with a solution?

PADGET: No. I must admit upfront that I don't have a surefire way to work these duties and activities into a pay-for-performance compensation system. Nor have I heard or seen where anyone else has either. Common sense and group member consensus-building are very important and you likely won't find two arrangements quite the same.

EDITOR: So what are some of the alternatives for handling Part A and related duties in a performance compensation system?

PADGET: Take one end of the spectrum—a relatively small, close-knit group. In this case, it might be reasonable and fair to simply ignore non-revenue generating activities altogether. This would be okay for a practice that's run in a highly democratic manner, in which all the work quite literally is shared equally among all the members. In essence, this treats non-revenue activities as "overhead" and says that each slide that's captured for income distribution bears the same amount of "overhead" as every other slide, regardless of which physician handles the slide or where it came from.

EDITOR: What's another method?

PADGET: Another fairly simple scenario is where one physician leader handles all practice administration duties plus the high-level lab medical director functions. All other non-revenue activities are shared equally among the other members of the group. Maybe the physician leader spends 70% of his or her time on functions other than direct patient care. What you can do here is reach consensus on how much 70% of the physician leader's time is worth. He or she is then paid that amount "off the top." All other non-revenue activities are treated as "overhead" as in the first scenario.

EDITOR: Is there another possibility?

PADGET: Yet another approach is to reach consensus on an hourly rate for non-revenue generating work. Then any given physician's compensation for a month is the sum of slides times slide-rate plus hours times hourly rate.

EDITOR: But this area is open to group discussion, debate, and compromise. What works for one group might not work for another group. Right?

PADGET: Correct. There is no single way, no "right way", to handle this. I think the only "wrong way" to handle this area is to ignore it in a situation where the work clearly falls most heavily on one or two pathologists. It doesn't take long before the inequity becomes a major political issue within the group and that's not a good thing to have happen. Beyond that, my general advice is: keep any system or formula as simple as possible.


Dennis Padget

We'd all like to believe that nobody in our group would ever try to "game" the system, but it's better to periodically test for this than to allow an issue to fester to the point where it becomes a major problem.

EDITOR: Okay, could you pull it all together for us? How does the system work from month-to-month?

PADGET: Conceptually, the math is straightforward. You start with next year's budgeted net income before shareholder-physician compensation. From that figure you subtract the compensation that will be paid to the doctors for their non-revenue generating duties. What's left is budgeted shareholder-physician compensation payable on a work-performance basis. Divide that number by the budgeted number of slides for the coming year to get your compensation per slide rate.

EDITOR: I'm with you so far. What's next? How do you figure how much to pay any one doctor for the month?

PADGET: Each month each shareholder-physician is compensated first for his or her non-revenue hours, or however else that set of duties is to be paid. Then you multiply the pathologist's slide count for the month by the compensation per slide rate to determine his or her production-based pay. That's about it.

EDITOR: Mr. Padget, thank you very much for sharing your ideas and suggestions with our readers.

PADGET: You're most welcome! TDR

Contact Dennis Padget at 502-722-8873.

Lab Industry Briefs

IMPLANTABLE HUMAN IDENTIFICATION CHIP CLEARED BY FDA

IT'S A DEVELOPMENT THAT INVOKES images from both George Orwell's *1984* and Aldous Huxley's *Brave New World*. An implantable radio frequency identification microchip (RFID) for human use was cleared by the U.S. **Food and Drug Administration** (FDA) for medical applications in the United States

On October 13, **Applied Digital** announced FDA clearance of its VeriChip™ Health Information Microtransponder. About the size of a single grain of rice, the device is inserted under the skin, usually in the triceps area of the upper arm. Each VeriChip has a unique 16-digit number that can be read when a radio scanner is passed over the skin. The 16-digit number is linked to a database through encrypted Internet access.

One human use of the VeriChip is to make a patient's healthcare information—via the VeriChip data base—available to healthcare providers. After accessing the 16-digit number code from the chip, physicians could then use the Internet to access those medical records. Because a major component of any patient's medical record is laboratory test data, lab executives and pathologists may want to track the market development of VeriChip.

In recent years, VeriChips have been used to identify pets and livestock. In one medical demonstration project, 1,000 patients in Mexico received VeriChips. Their blood type and other medical information was included in the database linked to their VeriChip. One unusual use was the implantation of VeriChips in 200 individuals working in the Attorney General's office in Mexico. The VeriChips were used to grant assess to secure areas where confidential documents and information was stored.

VeriChip is one demonstration of RFID technology. Because it is a device to be implanted in the human body, acceptance by patients and physicians may take some time. However, THE DARK REPORT believes that radiofrequency identification tags will eventually supplant bar code systems in many healthcare applications, including labeling and tracking lab specimens, patient identification, inventory management, and pharmacy uses. The rate of adoption will depend on how fast vendors can reduce the unit cost of the individual RFID tags.

LABCORP RELEASES EARNINGS REPORT FOR THIRD QUARTER 2004

ON OCTOBER 21, 2004, **Laboratory Corporation of America** announced its earnings for the most recent quarter.

Revenues were up 3.9%, from $752 million in Q3-2003 to $781.5 million in Q3-2004. LabCorp explained that 2% of the growth in revenue was due to increased specimen volume and about 2% was due to higher pricing. It also noted that the four hurricanes which struck across the Southeast during the quarter had impacted the expected volume of business for third quarter.

For the first nine months of 2004, LabCorp's revenues totaled $2.32 billion, which was a 5% increase over the first nine months of 2003. It stated that "testing volume, measured by accessions, increased approximately 4% and price increased approximately 1%" over the first nine months of 2003. TDR

INTELLIGENCE LATE & LATENT

Items too late to print, too early to report

At a steady rate, healthcare is evolving toward a fully-electronic, Internet-based informatics environment. Here are some noteworthy milestones that illustrate this progress. During 2003, consumers' use of the Web to access their health insurers' Web sites increased 94%! So reports the **Manhattan Institute** of New York City in a report titled "Hospital and Health Plan Segmentation." Consumers are using the Web this way because they like the ability to save time in accessing the information they need. Another milestone is the fact that high-speed Internet access eclipsed dial-up access for the first time this July. **Nielson NetRatings** reports that 63 million people used high-speed connections in their home that month, versus 61.3 using narrow-band connections.

MORE ON: Web Growth

In July, 58% of consumers used high-speed connections in their home, versus only 38% in July 2003. Lab directors and pathologists should recognize this continued advance in Internet adoption and develop more sophisticated Internet services for their patients and physicians.

CONSUMERS IN PA OPT FOR SURGERY CENTERS OVER HOSPITALS

In Pennsylvania, growing numbers of consumers are opting to use free-standing surgery centers and diagnostic clinics over hospitals. The **Pennsylvania Health Care Cost Council** (an independent state agency) recently reported that 19% of patients in that state choose to be treated in settings outside the hospital. It also noted that, between July 2003 and May 2004, 48 new ambulatory surgery centers (ASC) opened, giving the state 161 ASCs. Between fiscal 2001 and fiscal 2003, patient visits to ASCs jumped 80%, from 279,335 to 501,781.

ADD TO: PA Outpatients

This is rapid change over a three-year period and should be a warning sign to hospitals, hospital labs, and hospital-based pathology groups. As the trend towards consumer-directed healthcare picks up momentum, the Pennsylvania experience is powerful evidence that a growing number of patients want to be treated in non-hospital settings. In this study, it was also reported that the Pennsylvania ASCs were profitable, with an average operating margin increasing from 12% in fiscal 2002 to 16% in fiscal 2003. From a market share perspective, hospital laboratories and pathology groups need a business strategy that enables them to reach outside the hospital and offer diagnostic testing services to these free-standing surgery centers and the growing numbers of patients they serve.

BLUE CROSS OF NC TO TREAT OBESITY

Blue Cross Blue Shield of North Carolina will cover the cost of treating obesity. Experts call this a bold move for a major insurer. Coverage will include four physician visits annually, needed diagnostic tests, and counseling by dieticians. The insurer stated that 1.1 million of its beneficiaries will be eligible for this program.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 22, 2004.