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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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R. Lewis Dark
Founder & Publisher

Opportunities Ahead for Labs That Prepare

AT THE END OF EVERY YEAR, IT'S ALWAYS SMART BUSINESS FOR EVERY LAB to peer into the future specifically to identify the best clinical and financial opportunities. With the New Year just a few weeks away, this issue of THE DARK REPORT is designed to help you and your management team prepare for what's coming in 2016.

We offer you our overview of the most important healthcare macro trends on pages 3-6. This is to help you with your lab's strategic planning. The U.S. healthcare system is transforming and it is essential that your lab organization evolve in ways that keep it clinically relevant and financially viable.

At the same time, 2016 will not be all good news for the lab industry. CMS is ready to gather market price data during 2016 and use it to set Part B clinical laboratory test fees. Similarly, the FDA continues to push forward with its plans to regulate laboratory-developed tests. Both initiatives are expected to have negative financial consequences for the nation's medical laboratories and pathology groups. You'll read our summary of these developments on pages 7-8.

We urge you to incorporate all these insights into your lab's strategic plan while plotting a proactive course of action. Next year, no lab can do the same things it has done in the past five years and expect to see a satisfactory financial result by year end. What is true is that the changing needs of hospitals, physicians, and payers are creating new opportunities for labs to hold their own—and even prosper—when they introduce new diagnostic services that allow providers to use lab tests more effectively to produce improved patient outcomes while helping to reduce the overall cost of care.

After you read this issue of THE DARK REPORT, I encourage you to go back through all of 2015's output to refresh your understanding of how the innovative labs we profiled over the year are delivering value in new ways—and being financially rewarded as a consequence.

The examples are inspiring: integrated radiology/pathology at **UCLA**, diagnostic management teams at **Vanderbilt**, our introduction of the Laboratory Value Pyramid, genetic test utilization management at **Seattle Children's Hospital** and **Cleveland Clinic**, success with pharmacogenomics tests at **Mayo Clinic**, and 10 ways to add value at **Henry Ford Health**. We hope and expect that our research and reporting help your lab learn to add value! TDR

State of Clin Lab Industry Likely to Be Mixed in 2016

Review of healthcare's macro trends shows why labs must prepare for rapid pace of change

CEO SUMMARY: Over the next 24 months, it will be essential for every clinical laboratory and anatomic pathology group to develop clinical and financial strategies that meet the changing needs of health insurers, hospitals and health systems, physicians, and patients. THE DARK REPORT provides its assessment of key macro trends for 2016, along with comments about how first-mover lab organizations are delivering more value to stay ahead of these macro trends.

WITH 2016 JUST A FEW WEEKS AWAY, most clinical laboratory organizations face what may be the most challenging and complex market for healthcare and lab test services since the advent of managed care plans in the early 1990s.

These challenges complicate the strategic planning underway at many labs as they prepare for 2016 and lock down budgets, plans for capital spending, and business development goals. To assist in this effort, THE DARK REPORT offers its perspectives about the current state of the clinical laboratory industry, along with several key developments to expect during 2016.

Before reviewing this assessment, it is important to note that 2016 and beyond will be a time of accelerating change, particularly when compared with the 1990s and 2000s. Perceptive lab administrators and pathologists already understand this fact and are prepared to act decisively.

Macro trends within the American healthcare system involve several primary elements. Trend one is the shift toward integrated care delivery organizations, such as ACOs and patient-centered medical homes (PCMHs). Such entities assume total responsibility for the health of all beneficiaries for which they are responsible.

Leavitt Partners, in a study published in May, reported that 744 ACOs are in operation. This is an increase from 490 ACOs at the end of 2013.

There has been a similar growth in PCMHs, but no recent national numbers

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are available. However, Michigan illustrates the progress of PCMHs. In 2015, **Blue Cross Blue Shield of Michigan** stated that its network included 4,340 physicians in 1,551 practices who met the criteria of a PCMH.

Rapid growth in the number of beneficiaries enrolled in ACOs and PCMHs creates a challenge for clinical labs and pathology groups that want access to these patients. Integrated care organizations, to fulfill their mission of total care, need more from labs than simply a timely test result at the lowest price. They need labs to step forward and contribute to improving patient outcomes while lowering the overall cost per episode of care.

Trend two is the goal of delivering proactive care. Integrated care organizations are expected to reach out to beneficiaries and engage them to keep them as healthy as possible. This means ensuring that patients get screening services as appropriate, that patients with chronic diseases get the ongoing clinical care needed to effectively manage their conditions, and that early diagnosis, accompanied by active intervention, is accomplished whenever possible.

Labs Poised To Contribute

As ACOS and PCMHs work to achieve these goals, labs are positioned to make significant contributions. To do so, labs will need to become much more consultative with clinicians.

In the past year, THE DARK REPORT has profiled the efforts of the labs at the **Cleveland Clinic** *(TDR, June 1, 2015)* and **Henry Ford Health System** *(TDR, August 24 and October 5, 2015)* to deliver more value. Clinical pathologists at both institutions engaged physicians to improve lab test utilization while improving patient outcomes and saving money.

Trend three involves changes in healthcare payment models. "Volume to value" is the overused term, but it is particularly apt for the clinical lab profession. When labs are paid on a fee-for-service basis, more specimen volume has always meant lower average cost-per-test while optimizing profit margins.

But the Medicare and Medicaid programs have declared a timetable to move away from FFS payment. *(See sidebar on page 5.)* Similarly, private health insurers are negotiating more budgeted (capitated) payment agreements with hospitals, physicians, ACOs, and PCMHs. Often these agreements mean that the providers accept full utilization risk in exchange for a fixed per-member-per-month payment.

Provider Payment Reforms

The coming reforms to provider payment will have a substantial financial impact on clinical laboratories and pathology groups. Labs serving integrated care organizations will need to accept budgeted payment while doing much more than simply reporting accurate, timely test results.

Two of the first pathology groups in the nation to sign contracts with ACOs were profiled by THE DARK REPORT. In Milwaukee, **North Shore Pathology** is working with **Integrated Health Network of Wisconsin** *(TDR, March 30, 2015)*. Similarly, in Alabaster, Alabama, **CytoPath, PC**, contracted with the **Baptist Physician Alliance** *(TDR, March 9, 2015)*. Both pathology groups reported successes in reducing unnecessary lab test utilization in ways that produced significant cost savings to the respective ACOs while improving patient safety.

Payment For Reference Tests

Despite the shift toward new forms of value-based reimbursement, some reference and esoteric testing may continue to be paid as fee-for-service. This will be a result of client-billing arrangements reference labs have with hospitals, integrated delivery systems, and other labs,

But in trend four, even this segment of lab testing will be under extreme pricing pressure. Hospital clients—themselves getting paid a budgeted amount per patient—

Reminder: Medicare Program Has Aggressive Timetable to Shift Away from Fee-for-Service

MANY PATHOLOGISTS AND CLINICAL LAB MANAGERS ARE UNAWARE of the aggressive timetable the federal government has announced for replacing Medicare fee-service payments with alternative reimbursement models. On January 26, 2015, the federal **Department of Health & Human Services** announced this timetable.

It issued a press release titled, "Better, Smarter, Healthier: In historic announcement, HHS set clear goals and timeline for shifting Medicare reimbursements from volume to value." The federal agency said it was publishing these "measurable goals and a timeline to move the Medicare program, and the health care system at large, toward paying providers based on the quality, rather than the quantity of care they give patients."

Two Ambitious Goals

HHS described two goals, with an ambitious timetable for implementation. About the first goal, it wrote that, "HHS has set a goal of tying 30% of traditional, or fee-for-service, Medicare payments to quality or value through alternative payment models, such as accountable care organizations (ACOs) or bundled payment arrangements by the end of 2016, and tying 50% of payments to these models by the end of 2018."

Clinical labs and pathology groups should expect that, when CMS issues a draft of its annual Medicare Physician Fee Update in July 2016, a significant number of lab testing services will be covered in proposed bundled-payment arrangements. This will be done independently of the actions by CMS to set Part B clinical laboratory test fees using the market data reporting mandated by the Protecting Access to Medicare Act.

On the second goal, the press release stated that "HHS also set a goal of tying 85% of all traditional Medicare payments to quality or value by 2016 and 90% by 2018 through programs such as the Hospital Value Based Purchasing and the Hospital Readmissions Reduction Programs."

As a consequence of these plans, hospital laboratories and pathology groups serving community hospitals will want to anticipate these new value-based Medicare payment models with strategies for their labs to add value. Hospitals, including those participating in ACOs— face entirely new payment models based on improving patient outcomes and will be motivated to consider how their clinical labs and pathology groups can contribute to better patient care at lower cost.

HHS also called attention to a another noteworthy aspect of its press release. "This is the first time in the history of the Medicare program that HHS has set explicit goals for alternative payment models and value-based payments," it said.

A reason why the Medicare program declared its timetable to move away from fee-for-service is significant is that private health insurers will emulate what they like about these new provider payment arrangements. This is why lab executives should factor these developments into their lab's strategy planning activities.

will pressure their reference labs to slash prices. They might even ask reference labs to do all testing under capitated payment arrangements. Lab executives should anticipate these requests from accounts that use client billing arrangements.

Managing reference send-out testing to specialty genetic testing labs on client bill arrangements was covered by THE DARK REPORT in our issue of April 20, 2015. At **Seattle Children's Hospital**, the lab reported that it was being reimbursed, on average, about $350,000 for every $1 million of genetic tests it paid to its reference labs.

To improve utilization of genetic tests, the lab hired a genetic counselor and

helped physicians understand, at time of order, which genetic tests would be most appropriate. In the first eight months of the program, there was an average reduction of $463 per order on the cost of tests ordered using this management program.

Managed care contracting is the fifth macro trend and it has much in common with the integration of care, proactive care delivery, and new payment models as described above. That is because health insurers must alter their contracting practices in order to support these changes in healthcare delivery.

Narrow Provider Networks

Expanding enrollment in the ACA's health insurance exchange plans directly affects labs in two primary ways. First, exchange plans are narrowing networks in order to exclude high-priced hospitals, physicians, and clinical labs. The goal is to keep costs down so their premiums are competitive.

Second, the migration of Medicare Part B patients—16.8 million in 2015—to Medicare Advantage plans has major consequences for community labs. That's because Medicare Advantage plans typically have exclusive contracts with the national labs. As a result, local labs are steadily losing access to Medicare patients because of this shift.

Every lab that wants access to patients enrolled in Medicare Advantage and the ACA exchange plans must have a price and service strategy that appeals to these payers while delivering patient-centric services.

Trend six involves high deductibles in managed care plans. By design, patients are being asked to pay as much as $5,000 and $10,000 per year out-of-pocket to meet individual and family deductible requirements. Clinical labs must be prepared to quote prices before serving these patients, then have the capability to collect 100% of the cost of testing when the patient shows up for service. Few labs in the United States have either capability.

One success story, however, is **Counsyl, Inc.**, a clinical lab and technology company in South San Francisco. In our August 3, 2015, issue, THE DARK REPORT explained how Counsyl uses a web-based tool that enables patients to calculate how much they will pay for their genetic tests—before the physician orders their test. Payers like this patient-friendly feature too. Counsyl has managed care contracts that cover 80% of the commercial lives in the United States.

An equally significant trend in managed care contracting involves tougher hurdles for labs to gain favorable coverage and reimbursement decisions for new lab tests from both government and private payers. The Medicare MolDx program is one example that THE DARK REPORT has covered extensively in recent years.

Additionally, both Medicare and private insurers are seeing explosive growth in certain segments of lab testing. The increase in genetic tests is one example. The abusive billing practices in some areas of proprietary cardiology testing and pain management/drugs-of-abuse testing—as revealed by a growing number of successful federal lab whistleblower lawsuits against such labs—are among the reasons payers have become aggressive at denying coverage and rejecting more out-of-network lab test claims for these tests. *(See TDR, August 24 and September 14, 2015.)*

PAMA Market Price Reporting

THE DARK REPORT will address the issues involving PAMA market price reporting and the FDA's proposed regulation of laboratory-developed tests on pages 7-8. It is anticipated that these developments will have a negative financial impact on most clinical laboratories.

Not to be overlooked on this list of macro trends is the accelerating growth in the use of personalized and precision medicine. This macro trend will be addressed in an upcoming issue of THE DARK REPORT. TDR

Coming Next Year for Labs: PAMA, FDA, LDTs, and More

In 2016, the federal government is poised to reshape the lab testing marketplace radically

CEO SUMMARY: As 2016 approaches, nearly every lab organization is watching and waiting to learn how federal regulators at CMS and the FDA will move forward with plans to implement PAMA market reporting and regulation of laboratory-developed tests, respectively. Most knowledgeable observers expect that each government program will cost labs substantial amounts of money—from fee cuts to the Part B lab fee schedule and from the costs to comply with proposed LDT regulations.

ON TWO IMPORTANT FRONTS, the federal government is poised to reshape the clinical laboratory marketplace during 2016 and into 2017. There is the potential for every lab organization to experience significant financial consequences as a result of how federal officials move forward with just two regulatory initiatives.

One is the implementation of market price reporting by labs to the federal **Centers for Medicare & Medicaid Services** as mandated by the Protecting Access to Medicare Act of 2014 (PAMA). After issuing its draft rule this fall, the time for public comments closed on November 24.

The other is regulation of laboratory-developed tests (LDTs) by the **Food and Drug Administration**. The federal agency issued draft guidelines this fall and recently told Congress that it intended to move forward with its plan to regulate LDTs.*(See TDR, November 24, 2014.)*

Both federal regulatory efforts have met with widespread disfavor across the clinical laboratory industry. There has been plenty of criticism, but at the moment, lab professionals watching developments inside Washington, D.C., don't see much possibility that each of these draft regulations will either be stopped before implementation or modified significantly enough to allay the concerns of lab executives and pathologists.

Market Reporting Issues

Over the past year, THE DARK REPORT has provided insights about the problems with how PAMA defined lab price market reporting and how CMS proposed to implement that part of the law. The flaws in the draft rule are many and have the potential to create much disruption among clinical labs that provide testing to Medicare patients. *(See TDR, February 17, 2015, and October 5, 2015.)*

Of equal significance is the observation by some experts that, if the rule is implemented as currently written, many of the nation's smaller community labs—already surviving on thin profit margins—will go out of business. Because most of these labs serve mostly Medicare patients in smaller communities and in

nursing homes, as they shut their doors, Medicare patients in those communities will have a more difficult time gaining access to clinical lab testing services.

When Congress passed PAMA in 2014, the bill was scored as saving $2.5 billion in Part B clinical laboratory test fees over 10 years. Thus, the lab industry was caught by surprise when CMS released the draft market reporting rule this fall. It said that the rule would double the savings—$5 billion—over 10 years.

Lab professionals have reason to be concerned about this turn of events. In a study of Part B lab test claims and payments made in 2010, the OIG determined that just 20 tests make up 47% of all claims and represent 56% of CLFS payments made to labs that year. These 20 tests make up a substantial proportion of testing at most of the nation's smaller community labs. Thus, deep cuts to these prices are likely to cause many community labs to lose money, if not file for bankruptcy.

Proposed LDT Regulation

The consequences of the FDA's regulation of LDTs are causing much concern among another class of medical labs: those labs that perform LDTs that make up a substantial proportion of their specimen volume and revenue.

The **American Clinical Laboratory Association** (ACLA) says that the FDA lacks the statutory authority to regulate LDTs. Earlier this year, it retained attorneys Paul D. Clement, a partner with **Bancroft PLLC** and former Solicitor General, and Laurence H. Tribe, Professor of Constitutional Law at **Harvard University**, to represent it on the LDT issue.

It is a significant sign that the major lab companies that are members of ACLA may be prepared to litigate this issue in federal court. Thus, even as the FDA continues to move forward with its plans to regulate LDTs, it may face a serious court challenge that must be addressed before it can implement its rule to regulate LDTs. TDR

FDA Testifies to Congress About LDT Regulation

On November 17, at a hearing of the House Energy & Commerce Committee, House members heard testimony from the FDA and lab industry groups about the FDA's intent to regulate laboratory-developed tests (LDTs).

Jeffrey Shuren, MD, JD, is Director of the FDA's Center for Devices and Radiological Health (CDRH). In his testimony he defended the FDA's plans to regulate LDTs. He also referenced a newly-released report issued by the FDA and titled: "The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies." This study identified LDTs that were considered to be inaccurate enough to cause patient harm.

"The problems are more prevalent than people want to recognize," declared Shuren, "Doctors and patients rely on these tests to make well-informed healthcare decisions. If they get inaccurate results, they can make the wrong decisions, and people get hurt as a result."

There is a new twist in the story of FDA regulation of clinical lab tests. Prior to the hearing, the committee released a 185-page draft bill that described the creation of a new "Center for *In Vitro* Clinical Tests" within the FDA. The bill referred to the tests as "*in vitro* clinical tests" and there is uncertainty as to how, under this bill, the FDA would regulate the *in vitro* diagnostic clinical tests differently from *in vitro* diagnostics (IVDs).

Under this bill, the newly-created FDA center would be required to classify *in vitro* clinical tests as high-risk (if an inaccurate test result would cause serious harm, or death, to the patient), moderate-risk (if an inaccurate result for the intended use would cause non-life-threatening injury) and low-risk (meaning an inaccurate result would cause minimal or no harm, immediately reversible harm, or no patient disability).

Aurora Diagnostics Buys Toledo Pathology Group

Sale was result of local pathologist's strategy to access more capital and business resources

CEO SUMMARY: Consultants in Laboratory Medicine of Greater Toledo was sold to Aurora Diagnostics last month. CLM's president said that, as an ancillary service, pathology has little appeal to hospital administrators who want to cut costs as quickly as possible, and all hospital-based services are targets for cost reduction. Therefore, CLM sought a partner that could take over administrative functions so that its pathologists could focus on delivering added value to enhance patient care.

THINGS ARE GETTING TOUGHER for private pathology group practices. That's the opinion of one pathologist business leader who just sold his regional pathology company.

Last month, **Aurora Diagnostics** of Palm Beach Gardens, Florida, announced the acquisition of **Consultants in Laboratory Medicine of Greater Toledo, Inc**. CLM is a hospital-based practice with 16 pathologists.Terms were not disclosed.

F. Michael Walsh, MD, MBA, Chairman of the Department of Pathology and Medical Director of CLM, said the pathologists provide laboratory medicine and anatomic pathology services on an exclusive basis to 11 hospitals of the **ProMedica Health System**, a nonprofit health system serving 27 counties in northwest Ohio and southeast Michigan. The pathologists do not own the laboratories in those 11 hospitals.

The acquisition is one example of how the practice of anatomic pathology and laboratory medicine is changing quickly, Walsh said. "Over the past three years, we watched as markets contracted rapidly, health systems consolidated, were acquired, or have been forming integrated networks," he noted. "As these trends continue, every pathology group must have a big footprint in these newly-defined regional healthcare markets. Otherwise, they will be left behind.

Crunching the Numbers

"As much as we like to think it is not, pathology is an ancillary service to healthcare executives," he said. "Pathology has no special appeal to hospital administrators who look to reduce costs as fast as possible.

"As pathologists, we can emphasize how much added value we provide," Walsh continued. "But unless a group can truly reduce costs, it may not survive. It is essential for pathologists to show with hard numbers what they can do in terms of reducing costs both for their practice and the health system. At the same time, the pathology lab must show that it can exist and expand on its own without turning to the health system for financial support.

"What's happening here in Northeast Ohio is very similar to what's happening in

pathology nationwide," observed Walsh. "What's happening is difficult for pathologists because, in general, we don't actually know what's going on in the C suite, and these executives make decisions that are best for the hospital or health system without regard for what's best for pathologists.

"For these reasons, pathologists need to be involved in much larger organizations, ones that can afford to invest in the systems needed to make pathologists more efficient," he noted. "Those of us running pathology groups must understand the crucial importance of operating more efficiently. It's imperative to get the most out of the existing pathologists and staff. In today's healthcare system, it is no longer possible to simply add staff to increase productivity.

"Plus, we have to recognize that both pathology revenue and the number of surgical procedures are going down," Walsh added. "There will continue to be fewer surgical procedures because so many people now have high-deductible plans and they are choosing not to have surgical work done if they can avoid it.

"Another factor that is holding down revenue for pathology groups is the high levels of uncertainty in the health insurance market," commented Walsh. "It is expected that consolidation among the nation's biggest insurers will create still more downward financial pressure on smaller pathology groups.

"These are all reasons why the pathology profession needs to make advances in productivity," he noted. "One example is more effective use of digital imaging, but that requires capital resources that only exist in large pathology groups.

"Digital imaging is expensive and, because it's not certified for primary diagnosis, can only be done successfully by being part of a larger health system," he said. "It's fine for specialty consults and that's why it works in larger systems. In smaller systems, digital pathology will not yet pay for itself."

Following his own advice, Walsh sought a larger partner that could support a 16-member pathology practice while continuing to let them practice medicine.

"When we started to look for potential partners, we considered our own health system, ProMedica, and the **Cleveland Clinic**," he said. "We also considered a number of other pathology companies. We believe, however, that some pathology companies have reached a point of diminishing returns. They still knock on surgery center doors and say, 'Send us your work,' even as health systems acquire free-standing surgery and endoscopy facilities and internalize the work to their own labs.

"On the other hand, Aurora has a significant focus on hospital-based pathology groups and I believe that's where pathology's biggest strength and opportunity exists," noted Walsh. "That's because, in hospitals, we have the important role of integrating patient data and being directly engaged in patient care teams. Aurora clearly understand the importance of integrating patient data into all aspects of care and that is something that does not exist at other pathology firms.

An Attractive Partner

"Another reason we were attracted to Aurora is they moved quickly and that was important to us," Walsh added. "They also looked at where we are in terms of earnings before interest, taxes, depreciation, and amortization (EBITDA) and helped us set targets for our EBITDA. Aurora also took over all the back room functions, such as billing, contracting, and human resources. That lets us focus on practicing medicine.

"Here in Toledo, our pathology group will continue to operate as it always has and thus the hospitals and physicians will not notice any significant change," concluded Walsh. "Meanwhile, CLM has access to the capital and specialty expertise it needs to develop additional ways to help cuts costs and deliver more value to the hospitals we serve." TDR

—Joseph Burns

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Legal Update

True Health Diagnostics Sued by Cleveland Clinic and a Lab

Cleveland Clinic Foundation, Cleveland HeartLab claim True Health Diagnostics is infringing patents

IT'S GETTING DOWN AND DIRTY in the cardiology testing sector of the lab industry. No less than the **Cleveland Clinic Foundation**, along with **Cleveland HeartLab**, have filed a patent infringement lawsuit against a start-up lab in Texas.

The defendant is **True Health Diagnostics LLC**, of Frisco, Texas. In an amended complaint filed November 30 in the United States District Court for the Northern District of Ohio, Eastern Division, CCF and CHL claim that True Health Diagnostics is selling its proprietary cardiac-risk assessment test called Myeloperoxidase (MPO) and thus infringing on five U.S. patents that CCF owns and licenses exclusively to CHL.

Agreement with HDL

What adds color to this case is that True Health, founded in 2014, is the lab company that purchased **Health Diagnostics Laboratory** in a bankruptcy court auction in September.

It has been reported by some media outlets that investors and some executives of True Health are the same individuals named as defendants in a federal whistleblower lawsuit filed in Richmond, Virginia that seeks to recover $500 million and treble damages allegedly paid by the Medicare and Tricare programs to defendants **Berkeley Heartlab, Inc.**, **BlueWave Healthcare Consultants, Inc.**, Latonya Mallory, Floyd Calhoun Dent, III and Robert Bradford Johnson. *(See TDR, September 14, 2015.)*

Mallory, Dent, and Johnson were all associated with Health Diagnostics Laboratory, the cardiology testing lab that paid $47 million to the federal government to settle its part of the whistleblower case earlier this year.

As True Health has ramped up its sales program, competing labs have begun commenting that True Health is offering different forms of incentives to physicians to encourage lab test referrals—incentives that some competitors consider to be inducements that violate federal antikickback laws. Some of these comments can be found on postings at **CafePharma.com**.

CCF and CHL's lawsuit against True Health seems straightforward. It describes how executives at True Health declined to negotiate a license to offer the patent-protected assays. Instead, the court papers say that True Health began using a similar MPO assay by purchasing kits from **Diazyme**, which are for research purposes only.

CCF and CHL charge that True Health infringed on the five patents and asks the court for an injunction against the sale of these tests without authorization. The plaintiff labs also ask for a jury trial and triple damages. Further, if it is true that True Health is offering an assay for clinical testing that was only approved for research purposes, this would put the young lab company at risk of federal regulatory enforcement. TDR

—Joseph Burns

Letter to Fla. Doc Offers to Waive Lab Test Fees

➤Attorney believes that such arrangements may be false claims under state insurance regulations

➤➤CEO SUMMARY: Florida's highly-competitive market for lab testing services is again seeing some lab companies use "Waiver of Charges to Managed Care Patients" agreements with physicians in situations where the lab is an out-of-network provider. This means the lab will do free testing—waiving charges to the health plan and the patient—in order to keep the physicians' other lab test referrals. The physician must declare that he or she gets no remuneration or compensation because of this agreement.

ONE OF THE LAB INDUSTRY'S THORNIEST QUESTIONS about federal and state compliance is being asked in Florida. When is it permissible for an out-of-network laboratory to tell a physician it will do free testing and not bill a health plan or the patient?

This sales scheme involves "waiver of charges," a situation where an out-of-network lab tells a medical group it will not charge a specific insurer or that insurer's patients for lab tests as a business arrangement intended to persuade the physicians to continue using their lab, rather than the lab company that is in-network for that insurer. One purpose of "waiving charges" and doing free lab testing is to retain all the other lab test referrals of that physician, including patient self-pay, patients covered by other health plans, and patients enrolled in Medicare and Medicaid.

The "free testing" issue is surfacing again in Florida. It is believed to be a response by some lab companies to the exclusive lab testing contract for specific health plans that **UnitedHealthcare** has given to **BeaconLBS**, a business unit of **Laboratory Corporation of America**.

The free testing arrangement, known within public lab companies as "Waiver of Charges," refers to the Advisory Opinion issued by the Office of the Inspector General in December 1994. This opinion set out criteria that must be met if a provider or lab enters into an agreement with a physician not to charge a specific health insurance plan and its patients for lab tests it performs. *(See TDR, August 26, 2002.)*

➤Newer OIG Advisory Opinion

Additionally, waiver of charges is the specific issue addressed in the new OIG Advisory Opinion 15-04, released last March. Lab industry attorneys are studying this document to understand how it may change the guidance provided in the 1994 advisory opinion.

What makes Florida an interesting case study is that, along with the need for labs to follow federal law, the Sunshine State has its own regulations to deal with inducement and kickbacks.

One lab company known to be using the "waiver of charges" business scheme

of free lab testing in Florida is **Quest Diagnostics Incorporated**. Some lab competitors believe this is probably a response to UnitedHealthcare's laboratory benefit management program.

But, in fact, Quest Diagnostics has been out of the UHC network since 2007. That's the year when UHC established a national lab contract with LabCorp, eliminating Quest as an in-network option for UHC members, a UHC spokesperson said, further adding that Quest's out-of-network status "has nothing to do with the BeaconLBS lab utilization effort."

Out-of-Network Fees Waived

In a letter that appears to come from Quest Diagnostics and has been sent to a family physician, Quest offers to waive out-of-network charges for managed care services. The letter went to at least one physician in Florida and is signed by a physician in Southwest Florida and dated May 5, 2015. At the physician's request, THE DARK REPORT agreed not to disclose the name of the doctor who signed the letter.

The letter is not printed on any letterhead. It is not clear how many physicians received the letter or how many physicians returned the letter.

The first line of the letter explains that Quest Diagnostics is seeking to gain the out-of-network business for UnitedHealthcare's fully-insured products and those of **Golden Rule**, the **Empire Plan**, **United Medical Resources**, and **Oxford**. There are reports that this letter has been used recently with physicians in other states.

Quest Provides Statement

When asked about this letter and its use, Wendy H. Bost, Director, Corporate Communications at Quest, told THE DARK REPORT that, "Quest Diagnostics carefully evaluates our billing practices and has a vigorous compliance policy designed to comply with applicable laws and regulations. We have reviewed the March 2015 OIG advisory opinion (AO 15-04). Our position on this recent AO is aligned with that of our trade group, the **American Clinical Laboratory Association** (ACLA). You may want to contact them for more information."

One attorney who was asked to read the waiver of charges letter and comment said it could be an attempt to establish an illegal kickback arrangement with referring physicians. Asking not to be identified, this attorney said that the letter asks the physician to declare that he or she has no financial or business interests in the health plan in order to protect the physician from violating the self-referral rules.

Another attorney who saw the waiver of charges letter given to the Florida doctor is J. Marc Vezina, of the **Vezina Law Group** in New Orleans and Birmingham, Michigan. The letter could be the basis for a False Claim Act violation, and possibly could be a violation of Florida state insurance rules and regulations, he said.

Driving Marketshare

"My preliminary analysis is that this is a straight kickback arrangement—nothing more, nothing less," Vezina declared. "This is clearly an arrangement in which Quest is driving marketshare, and therefore utilization, in exchange for waiving patients' fees. In that way, the letter plainly describes a kickback arrangement that could be illegal under the Anti-Kickback Statute. Quest Diagnostics is saying, 'If you give us your marketshare we will waive the fees for your patients.'"

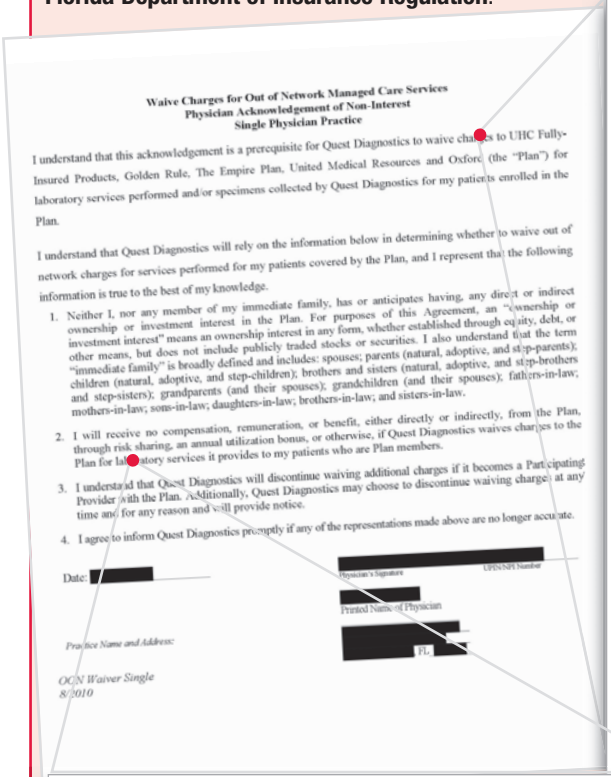
Vezina recently represented a whistleblower in a False Claims Act case against **Millennium Health** in which the **U.S. Department of Justice** alleged in part that Millennium engaged in practices that violated the Anti-Kickback Statute. That matter was settled when Millennium agreed to pay $256 million. Vezina's client was awarded a whistleblower's share of the settlement. *(See TDR, November 16, 2015.)*

When a Physician Affirms No Remuneration, 'Waive Charges' Letter Means Free Lab Tests

REPRODUCED BELOW IS A COPY OF A LETTER GIVEN TO A PHYSICIAN IN FLORIDA by a representative of Quest Diagnostics Incorporated. In the letter, Quest Diagnostics says it will not submit lab test charges to "UnitedHealthcare Fully-Insured Products, Golden Rule, The Empire Plan, United Medical Resources and Oxford."

The OIG Advisory Opinion of December 1994 addressed what is known as "Waiver of Charges to Managed Care Patients" as it relates to federal anti-kickback statutes. The opinion was intended to allow an out-of-network provider to continue serving a physician. The OIG issued Advisory Opinion 15-04 in March which is an update to its guidance on this matter.

At the state level, Florida has a law that addresses this situation. J. Marc Vezina, of the Vezina Law Group in New Orleans and Birmingham, Michigan, believes that an arrangement as described in the letter reproduced below could be the basis for a false claim under rules of the **Florida Department of Insurance Regulation**.



Waive Charges for Out of Network Managed Care Services
Physician Acknowledgement of Non-Interest
Single Physician Practice

I understand that this acknowledgement is a prerequisite for Quest Diagnostics to waive charges to UHC Fully-Insured Products, Golden Rule, The Empire Plan, United Medical Resources and Oxford (the "Plan") for laboratory services performed and/or specimens collected by Quest Diagnostics for my patients enrolled in the Plan.

I understand that Quest Diagnostics will rely on the information below in determining whether to waive out of network charges for services performed for my patients covered by the Plan, and I represent that the following information is true to the best of my knowledge.

1. Neither I, nor any member of my immediate family, has or anticipates having, any direct or indirect ownership or investment interest in the Plan. For purposes of this Agreement, an "ownership or investment interest" means an ownership interest in any form, whether established through equity, debt, or other means, but does not include publicly traded stocks or securities. I also understand that the term "immediate family" is broadly defined and includes: spouses; parents (natural, adoptive, and step-parents); children (natural, adoptive, and step-children); brothers and sisters (natural, adoptive, and step-brothers and step-sisters); grandparents (and their spouses); grandchildren (and their spouses); fathers-in-law; mothers-in-law; sons-in-law; daughters-in-law; brothers-in-law; and sisters-in-law.
2. I will receive no compensation, remuneration, or benefit, either directly or indirectly, from the Plan, through risk sharing, an annual utilization bonus, or otherwise, if Quest Diagnostics waives charges to the Plan for laboratory services it provides to my patients who are Plan members.
3. I understand that Quest Diagnostics will discontinue waiving additional charges if it becomes a Participating Provider with the Plan. Additionally, Quest Diagnostics may choose to discontinue waiving charges at any time and for any reason and will provide notice.
4. I agree to inform Quest Diagnostics promptly if any of the representations made above are no longer accurate.

Date: [redacted]

Physician's Signature [redacted] UPIN/NPI Number

Printed Name of Physician [redacted]

Practice Name and Address: [redacted] FL

OCN Waiver Single
8/2010

I understand that this acknowledgement is a prerequisite for Quest Diagnostics to waive charges to UHC Fully-Insured Products, Golden Rule, The Empire Plan, United Medical Resources and Oxford (the "Plan") for laboratory services performed and/or specimens collected by Quest Diagnostics for my patients enrolled in the Plan.

I understand that Quest Diagnostics will rely on the information below in determining whether to waive out of network charges for services performed for my patients covered by the Plan, and I represent that the following information is true to the best of my knowledge.

1. Neither I, nor any member of my immediate family, has or anticipates having, any direct or indirect ownership or investment interest in the Plan.

2. I will receive no compensation, remuneration, or benefit, either directly or indirectly, from the Plan, through risk sharing, an annual utilization bonus, or otherwise, if Quest Diagnostics waives charges to the Plan for laboratory services it provides to my patients who are Plan members.

and...

4. I agree to inform Quest Diagnostics promptly if any of the representations made above are no longer accurate.

"To the extent that these five health insurance plans identified in the letter do insure Medicare, Medicaid, military, or other beneficiaries in federal or state programs, this letter would clearly implicate the False Claims Act, as well as other federal and state anti-fraud statutes," Vezina said. "In addition, this process could implicate federal and state antitrust and consumer protection statutes.

"An out-of-network laboratory can benefit itself and the client physician if it waives the patients' charges and has the physicians continue to refer patients to it," he noted. "First, the arrangement obviously benefits the lab because it gets work it probably wouldn't get because it is not an in-network provider.

"Second, it benefits the plan member who is not charged a fee for going out of network," continued Venzina. "Normally, a patient going out of network would be charged a fee for doing so and that fee usually is much higher than going to an in-network laboratory."

Not Much Resistance

Vezina further noted that offering free lab testing under the waiver of charges scheme doesn't generate much resistance from physicians and their patients. "The point of this arrangement is that the physician and patient don't care either way and so they are not likely to complain to the health plan," Vezina said. "When you have a grey area like that, it's just ripe for fraud."

Patients and physicians may not care that the payer will not be charged by the out-of-network lab. But the health plans do have major concerns about this lab sales scheme. Several health insurers have sued lab companies over the failure of these labs—as out-of-network providers— to provide lab testing services but then not bill the patients.

Earlier this year, **Cigna** sued **Health Diagnostic Laboratory** in Richmond, Virginia, for waiving patients' copayments, thus encouraging patients to use doctors who would send their lab test work to HDL. By waiving copayments, HDL was subverting Cigna's attempts to steer patients to low-cost labs, Cigna said in court documents.

Another insurer that sued HDL was **Aetna**. It made similar claims in its court filings. In 2014, Aetna also sued **Biodiagnostic Laboratory Services** of Parsippany, New Jersey. BLS executives and as many as 30 physicians were found guilty of criminal charges in the federal anti-kickback case. Among the claims that Aetna made is that BLS waived patient co-pays on lab services to encourage patients to choose BLS.

Risk From Qui Tam Lawsuits

Meanwhile, lab companies using the waiver of charges sales strategies have another risk. It is from federal and state *qui tam* lawsuits filed by whistleblowers who are often employees of the lab, sales reps from competing labs, or physicians who consider the arrangement to be an illegal inducement. TDR

—Joseph Burns

Contact J. Marc Vezina at 248-558-2701 or jmv@vezinalaw.com.

OIG Advisory Opinion 15-04 Unfavorable to Requestor

THIS SPRING, the Office of the Inspector General released Advisory Opinion 15-04. It was a response to a request for an opinion from a "multi-regional medical laboratory," about certain arrangements where, for a referring physician, the laboratory would waive charges for a certain "Exclusive Plan."

Based on its analysis of the situation, the OIG wrote: "we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute." This opinion is now being studied by lab industry attorneys.

Compliance Update

UnitedHealthcare Comments on Labs' Use of 'Fee Waivers'

Enticing patients with offer to waive fees undermines health insurers' efforts to manage population health

PATHOLOGISTS AND LAB SCIENTISTS are familiar with the well-known scientific principle that, "for every action, there is a reaction." This principle also holds true for the managed care contracting practices of the two national laboratory companies.

One action that is the subject of this story is the award, in 2007 by **UnitedHealthcare**, of a 10-year, exclusive national contract to **Laboratory Corporation of America**. One reaction came just a few months later, when **Aetna**, Inc., awarded an exclusive national contract to **Quest Diagnostics Incorporated**.

In the ongoing battle of action/reaction between the two national lab companies, the need to retain and increase market share to keep Wall Street happy is the motivation for a lab to aggressively push back as an out-of-network provider.

As noted on pages 12-15, in Florida, and possibly in other states, Quest Diagnostics is using the "Waiver of Charges" sales strategy of doing free testing to encourage doctors to continue using it when Quest is out of network. The "Waiver of Charges to Managed Care Patients" was addressed in an OIG Advisory Opinion of December 1994. The OIG also addressed this matter in Advisory Opinion 15-04, released earlier this year.

In a waiver of charges letter from Quest to a physician in Florida, the letter identifies specific UnitedHealthcare insurance plans, including those that are in the laboratory benefit management plan that is managed by **BeaconLBS**, a business division of **LabCorp**.

When asked about the use of the free testing, or "Waiver of Charges" tactic, Elizabeth Calzadilla-Fiallo, UHC's Director, Public Relations for Florida and the Gulf States Region, made this statement to THE DARK REPORT: "Efforts to purposely steer patients away from their in-network labs and to non-participating providers is disingenuous and jeopardizes the patients' ability to maximize the insurance coverage that's available to them and that they've paid for." She would not elaborate nor answer questions about what steps UHC has taken to keep out-of-network labs from enticing patients with offers to waive charges.

UHC has been aware that the "Waiver of Charges" letter has been used since about 2010, and UHC has had several conversations with Quest Diagnostics in which it asked the lab to stop offering to waive charges, Calzadilla-Fiallo said.

Keeping Members In-Network

UnitedHealthcare has good reasons to keep its members in-network. That's because, like all health insurers, it needs the data it gets from clinical laboratory testing results for two reasons. One is to track appropriate utilization of services. The second is to better manage patient care, particularly by identifying gaps in care and helping providers close those gaps. TDR

—Joseph Burns

Theranos Update

Washington Post: Theranos Approached Military in 2012

Newspaper also reported that a DOD official 'sounded the alarm' and notified the FDA

SINCE THE WALL STREET JOURNAL published its exposé of **Theranos Inc.** in October, other media outlets have published the findings of their own investigations into various aspects of the lab company's practices.

One example is the disclosure by *The Wall Street Journal* in November that Theranos had an agreement with **Safeway** to put blood collection and testing centers in 800 Safeway stores. The *Journal* reported that Safeway had spent $350 million to build the collection and testing facilities needed in these stories, but that Theranos had not delivered the test equipment and collection staff that was its part of the agreement. *(See TDR, November 16, 2015.)*

Within weeks of this news, Safeway and **Sonora Quest Laboratories** of Mesa, Arizona, announced that SQL would provide patient service centers in two Safeway stores in Scottsdale and Phoenix. This is apparently a pilot project between the two companies. SQL sees an opportunity to build patient service centers in more of the 80 stores Safeway operates in Phoenix.

On December 2, the *Washington Post* reported on dealings that Theranos had with the **Department of Defense**. According to the Post, in 2012, the DOD requested that the FDA conduct a formal inquiry, writing "an official evaluating Theranos' signature blood-testing technology for the Department of Defense sounded the alarm in 2012 and launched a formal inquiry with the Food and Drug Administration about the company's intent to distribute its tests without FDA clearance." *The Wall Street Journal* raised similar questions about Theranos' technology and its relationship with the FDA in its reporting this fall.

After the DOD asked about FDA clearance, the Post said that it had reviewed email correspondence showing that Theranos CEO Elizabeth Holmes asked James Mattis, a four-star general with the U.S. Marines, to intervene on the lab company's behalf.

Holmes asked Mattis to dispel what she called "blatantly false information" about the company and that violating FDA rules was something the company has "never done and of course would never do," Holmes wrote, the Post reported.

Avoiding Regulatory Review?

The Post quoted from another mail, writing that, in a message to Mattis, Holmes wrote, "I would very much appreciate your help in getting this information corrected with the regulatory agencies. Since this misinformation came from within DOD, it will be invaluable if this information is formally corrected by the right people in DOD." Mattis has been a director at Theranos.

The Post further wrote that, "In a statement Theranos gave to the Post, "Theranos said the military was interested in modifying its [Theranos'] blood tests for a rugged battlefield environment, a pilot research project that would not have required standard regulatory approval.

But the military reviewer's concerns apparently were broader than that project and foreshadowed Theranos's current problems with the FDA."

Alert pathologists and lab administrators will note the reference by Theranos that the proposed pilot research project involving the DOD "would *not* have required standard regulatory review." This could be interpreted as an attempt by Theranos to get its proprietary lab analyzer and diagnostic technology into a setting where it could access real patients before having to submit this technology to the FDA for the agency's review.

Lab Testing For Military

The Post's reporting is consistent with what multiple sources within the DOD's military laboratory organization have told THE DARK REPORT. They say that a meeting took place in early 2013 at a military installation in Maryland. Theranos was there to show a portable lab testing device that it proposed could be used in military labs and in field hospitals.

Individuals who participated at this meeting say that a blood specimen was collected by Theranos at the start of the meeting to demonstrate the device. Several hours later, when the meeting adjourned, the device had been unable to produce test results. These sources say that DOD officials at this meeting also pointed out to the Theranos officials that a 70-pound lab test instrument would not be considered "portable" for military applications.

Given the news coverage that has happened since *The Wall Street Journal's* exposé of Theranos published on October 15, one common insight emerges: Theranos has struggled in recent years to demonstrate to third parties that its diagnostic technology can perform to expectations. As Theranos has said, it needs a fingerstick collection, a microspecimen, and a four-hour test result to be a potential disrupter of the clinical lab industry. TDR

—Joseph Burns

CLIA Inspectors Visited Theranos' Scottsdale Lab

LAST MONTH, the *Arizona Republic* reported that officials from the **Arizona Department of Health Services** conducted an inspection on April 2 of Theranos' lab in Scottsdale. The inspection was done on behalf of the federal **Centers for Medicare & Medicaid Services**.

Pathologists and lab managers will note that, while the inspectors reported four "deficiencies" at the lab, each one was routine and typical of such inspections in most clinical labs. Theranos told lab inspectors that it expects the Scottsdale lab will run 1.35 million tests annually.

The inspectors cited issues related to proficiency testing, validation of blood sample analyzers, humidity levels outside of acceptable ranges for some instruments, and deficiencies in dating blood-sample collections, the newspaper reported.

In the article, the Republic reported comments from Theranos saying the inspection findings were routine and that all issues were addressed or corrected within days or weeks of the inspection. Also, Theranos said the inspection findings did not reflect the reliability or accuracy of the consumers' tests, the newspaper added.

Following the Republic's report, Holmes wrote to the newspaper to say, "The piece wrongly implies that the observations may have impacted the accuracy of testing results when the simple fact, as we explained to the reporter, is that none of the issues that the surveyors identified impacted the accuracy or reliability of tests or patient results, and observations are common to all lab inspections."

It should be noted that Theranos has acknowledged to various media outlets that, for most of its clinical testing, it is using venous blood specimens and conventional lab analyzers. This is probably what the CLIA inspectors saw during their inspection.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last week, a joint laboratory accreditation agreement was announced by **AABB** and the **American Association for Laboratory Accreditation** (A2LA). The two associations will now collaborate to allow labs to obtain three assessments under one effort, including AABB accreditation, ISO 15189 accreditation, and CLIA requirements. In their statement about the benefits of the new arrangement, the two associations said that the assessment will be "against an ISO standard that is not prescriptive and can be implemented based on the [lab] organization's work culture and processes."

MORE ON: *AABB/A2LA*

One "behind the scenes" element in this agreement to offer a three-standard accreditation service is that both AABB and A2LA recognize the role that a quality management system (QMS) such as ISO 15189 can play in helping labs better manage costs while simultaneously identifying and reducing systemic errors in ways that improve patient safety. At a time when the public and the media are starting to hold clinical labs to a higher standard of quality and patient safety, this new accreditation service may find a ready welcome with lab administrators wanting to keep their lab organizations at the front edge of innovation and clinical excellence.

FDA SENDS LETTERS

Last month, the FDA sent letters to three genetic testing companies. The federal agency said they were marketing unapproved tests directly to consumers. The three companies were: **DNA4Life**, **DNA-CardioCheck, Inc.** and **Interleukin Genetics, Inc.** The letter requested that the lab companies either show that the tests have been cleared, or provide their rationale for why the tests do not need to be cleared. Last September, the FDA sent a similar letter to **Pathway Genomics**, questioning the clinical validation of its cancer detection test. Independent of the FDA's efforts to regulate LDTs, the agency is demonstrating that it intends to assert its authority to regulate genetic tests.

TRANSITIONS

- Edward D. Dooling, Jr., recently founded and is now the CEO of **Vanguard Healthcare Staffing**, based in Sparta, New Jersey. He has held executive positions at **American Pathology Partners**, **Asterand**, **AmeriPath**, and **Dianon Systems**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...the study published in the *American Journal of Clinical Pathology* by **Rice University** researchers about the variability of successive drops of capillary blood when testing for the cellular components of whole blood. The researchers recommended that other studies be conducted to confirm their findings.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 28, 2015.

By Demand!

Executive Leadership Development at the *Executive War College*!

Offering Mentoring for Young Lab Leaders

Special Opportunities for Mentors and their Mentorees

Now, more than ever, your lab or pathology group needs strong leaders. Our special Mentor/Mentoree sessions at this year's *Executive War College* are the lab industry's first-ever opportunity for you to bring your lab's brightest management up-and-comers and, by working together, master the essentials of an effective mentoring relationship.

This is a follow-up to last year's successful Executive Leadership Workshop that was conducted by Colonel Jeffrey D. McCausland (retired), former Dean of Academics at the U.S. Army War College. Today's lab leaders know the importance of mentoring the management talent who will be the lab's future leaders. At the upcoming *Executive War College,* you'll have the opportunity to "walk the walk" together with your most promising young leaders and accelerate their contributions to your lab's clinical and financial success. **Mark April 26-27 on your calendars and stay tuned for more details!**

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