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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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Commentary & Opinion by...

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Lab Whistleblowers Are an Ever-Present Threat

EVERY PATHOLOGIST, LAB MANAGER, AND INDUSTRY EXECUTIVE has a justified fear of whistleblowers in their laboratory or company. Whistleblowers can surface at the most unexpected moment and with the most devastating consequences.

As you will read in this issue of THE DARK REPORT, criminal actions against ex-employees of both **UroCor, Inc.** and **Impath, Inc.** were concluded last month. Whistleblowers played a key role in the UroCor case, but were not a factor in the Impath case.

On the subject of whistleblowers, I find the UroCor case to be most instructive. During the second half of the 1990s, a time when UroCor was growing at gangbuster rates, at least three separate *qui tam* lawsuits were filed by current or former UroCor employees. Sometime in 1997 or 1998, federal prosecutors decided to join these whistleblower cases and they were consolidated into a single legal action. As they reviewed whistleblower materials and other documents, federal investigators decided that the actions of several UroCor executives were in violation of anti-kickback and securities laws. These investigators contacted the U.S. Attorney's Office and made a criminal referral of several UroCor executives.

After investigating company business practices, reading company documents, and interviewing a host of laboratory personnel, the U.S. Attorney's Office became convinced that at least three executives of UroCor had committed actions that violated the Medicare anti-kickback statute and securities laws. In June 2004, criminal indictments were filed against these individuals. Following a three-week jury trial in June 2006, they were acquitted on all counts.

It's easy to characterize this situation as the worst nightmare for many pathologists, lab managers, and industry executives. Whistleblowers emerge from the lab organization, focus the attention of civil and criminal investigators on certain business practices and certain people. Criminal indictments are issued against key lab leaders. Then, following months and years of legal expense and stress, these lab leaders are (hopefully) exonerated in court by a jury of their peers. It's one example of how lab whistleblowers, whether well-informed or ill-informed, can stir up a hornet's nest of trouble.

Three Ex-UroCor Execs Acquitted in Jury Trial

Federal prosecutors were pursuing charges of anti-kickback violations

CEO SUMMARY: On June 30, 2006, three former executives of UroCor, Inc., accused by the U.S. Attorney of anti-kickback and securities violations, stood and heard the jury verdict in their case. "Not guilty on all counts," stated the jury foreman. Thus ended the effort to convict former executives of a public lab company of violating Medicare anti-kickback laws because of how they used certain sales and marketing practices.

LAST MONTH, THREE FORMER EXECUTIVES of **UroCor, Inc.**, accused of violating federal anti-kickback and securities laws, went toe-to-toe with the U.S. Attorney in a criminal trial in Oklahoma City and convinced the jury to vote for acquittal on all counts.

This trial is a significant event for the laboratory industry. That's because, whenever the federal government issues criminal indictments against laboratory managers for violating Medicare laws, it is the ultimate enforcement action. Therefore, the indictment, pre-trial maneuvering, the trial itself, and the final decision by the judge or jury offer useful insights about how government healthcare prosecutors believe the laws should be interpreted, obeyed, and enforced.

The UroCor case is noteworthy for another reason. THE DARK REPORT believes this case is the first time that federal prosecutors have indicted executives from a public laboratory company for criminal violations of federal anti-kickback laws. Most high-profile criminal convictions of executives from public laboratory companies during the past 15 years have been for violating Medicare fraud and abuse statutes or securities laws. *(See TDR, June 20, 2005.)*

In this case, two of the three ex-UroCor defendants were accused by the federal attorney of anti-kickback violations during the years 1993-1999. As described in the indictment, these violations stemmed from discounted pricing and similar marketing prac-

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tices commonly used to sell laboratory testing services.

Because of this line of reasoning, the trial and its acquittal have many compliance lessons to teach. However, for reasons to be explained elsewhere in this issue, the UroCor trial and its outcome is likely to increase confusion rather than to add clarity.

Count One: Anti-Kickback

Facing one count of "conspiracy to provide kickbacks" in violation of Title 42, United States Code, Section 1320a-7b(b)(2)(A) was William A. Hagstrom (Chairman, President and CEO from 1989 through 1999) and Mark G. Dimitroff (employed at UroCor from 1990 to 1999 as Vice President of Sales and Marketing).

Facing a second count of "conspiracy to commit securities fraud in violation of Title 18, United States Code, Section 371" was Hagstrom and Michael N. McDonald (employed from 1992 to 1999 as Chief Financial Officer). These two indictments were announced on June 16, 2004 by Robert G. McCampbell, United States Attorney for the Western District of Oklahoma. *(See TDR, July 19, 2004.)*

The trial, which commenced on June 12, 2006, lasted almost three weeks. The jury deliberated approximately seven hours and acquitted all three defendants on all counts.

Discounted Pricing

In the anti-kickback portion of the trial, discounted pricing, also known as "client billing," was one sales practice that was scrutinized. In the indictment, "the offer of 'special pricing' discounts" is described as a criminal act, saying that "Hagstrom and Dimitroff and other unindicted co-conspirators encouraged UroCor sales representatives to offer substantially discounted pricing for laboratory tests for non-Medicare patients in return for the referral of Medicare business. Discounted or 'special pricing' was offered to those doctors who the sales representatives determined were 'hard-to-close' accounts and had a significant number of Medicare patients. UroCor priced some laboratory tests substantially below the Medicare reimbursable rate and in some cases below UroCor's own cost of performing the tests."

Prosecutors zeroed in on the fact that, in some cases, UroCor's price to some physicians was less than its marginal cost, even as it continued to submit claims to Medicare for full reimbursement. The indictment lists the Medicare reimbursable rate for a PSA test in 1994 as $27.33. It also documents how UroCor offered doctors a PSA rate of $12.00 in 1992 for non-Medicare patients. This rate was lowered to $7.00 in 1994 and further lowered to $5.50 in 1997. UroCor priced PSA tests to at least one urology client at $2.75 per test.

Defense Arguments

During the trial, Hagstrom and Demitroff's attorneys rebutted these points with some arguments that will surprise many attorneys and laboratory managers who closely study laboratory compliance. These arguments are covered in more detail in the story on pages 9-16.

UroCor was accused of criminal anti-kickback violations involving two other sales programs it offered during the years 1993-1999. One program was known as IRA, which stands for insurance reimbursement assessment. Between 1992 and 1999, UroCor used this sales tactic in situations where it did not hold managed care contracts.

UroCor used the program to encourage doctors to send all their laboratory business to UroCor, including

Medicare and out-of-network specimens. The federal attorney claimed that this program provided a benefit to doctors by saving staff time that would be spent packaging and sending the specimens to different laboratories as required by their patients' managed care plans.

On this subject, the indictment continues, "In return for doctors agreeing to send UroCor all their laboratory business during the term of the IRA agreement (including their Medicare business), UroCor agreed to accept as full payment any amount (including a full denial of benefits) paid by managed care organizations to out-of-network providers, such as UroCor, for the patients' laboratory services. In addition, UroCor agreed not to send statements to managed care patients for any balance not paid by the patient's insurance when UroCor was an out-of-network provider. This eliminated doctors' concerns that their patients would be penalized financially as a result of the doctor using an out-of-network lab."

Pacts Never Terminated

In describing the impact of this tactic, the indictment makes these points: 1) the IRA agreement forms stated that they were to last 90 to 180 days. In reality, "the agreements remained in effect until the program was terminated in April 1999"; 2) IRA agreements were offered "to doctors whose volume of Medicare business assured profitability to UroCor...Neither the Medicare program nor its patients received any benefit from UroCor under an IRA agreement."

The indictment next states that Hagstrom and Dimitroff were advised, "by legal counsel, government fraud alerts, and UroCor employees" that such IRA agreements needed to be cancelled after the 90- to 180- day expiration to avoid concerns that they were inducements to the doctor in return for referral of Medicare patients. The point about the lawyers' advice on this and other compliance topics came up during the trial and was used by federal prosecutors. It will be commented upon in the story found on pages 9-16.

Most Federal Indictments Lead to Convictions

IT IS WORTH NOTING TWO UNUSUAL ASPECTS involving the indictment and trial of the three ex-UroCor executives. First, none of the three decided to resolve their case by a plea bargain. Second, the three defendants showed unity and presented a common defense against the criminal allegations facing them.

The conviction behind these decisions is best illustrated by the odds they faced. "Statistics show that 95% of all federal indictments are resolved by a plea bargain with the defendant," stated Reid Robison, attorney with **McAfee Taft** in Oklahoma City, Oklahoma. Robison was lead counsel for defendant WIlliam Hagstrom.

"The remaining 5% of federal indictments go to trial," continued Robison. "Seventy-five percent of those defendants are convicted." Using Robison's statistics, for every 100 people indicted of a federal crime, less than two will be acquitted.

Facing these odds, the decision by the three defendants to plead "not guilty" and go to trial can be taken as a sign of their earnest belief that they had violated no laws. And since federal prosecutors can create incredible pressure to get a single defendant to agree to provide evidence for the state, the fact that none of the "UroCor Three" decided to accept a plea bargain agreement and testify against the other two further reinforces that conclusion.

UroCor put IRA agreements to extensive use. At one point, IRA agreements were approved and in effect for 800 doctors.

As described in the indictment, UroCor's IRA agreements allowed it to get a physician's account even though it was an out-of-network provider for one or more of the key managed care plans that covered the physicians' patients. UroCor would not charge the managed care plan for the test, nor would the physician or patient get a bill for that test.

...UroCor's IRA agreements allowed it to get a physician's account even though it was an out-of-network provider for one or more of the key managed care plans that covered the physicians' patients.

This arrangement resulted in "free testing." It seems to have close parallels to the "waiver of charges to managed care patients" tactic enabled by the OIG's fraud alert of December 1994 and used in today's lab marketplace by a number of laboratory companies. This is another point that was raised during the jury trial.

The final program identified in the indictment as a violation of anti-kickback laws was UroCor's use of consulting services contracts. As described in the indictment, to retain a urologist's business, UroCor would enter into a "consulting services agreement." A sum of money was to be paid to the doctor. The doctor, per the agreement, was to document the consulting services provided to UroCor in monthly reports. The indictment goes on to list examples where UroCor payed specific urologists amounts totaling $36,000 to $75,000 per year and noted that there was no evidence that any of these urologists filed a monthly statement documenting the consulting services they provided UroCor in return for these payments.

In the second count, which covered violations of the securities laws, Hagstrom and McDonald were accused of such things as misleading investors when making public statements, withholding information and misleading its public accounting firm during audits, and booking revenues from tests for which it never intended to bill. (This violation is linked to how UroCor was accounting for specimens covered under the IRA agreements, for which it would not bill payer, physician, or patient.)

Securities violations claimed in this count don't relate closely to clinical laboratory and pathology group compliance with Medicare fraud and abuse, anti-kickback, and self-referral (Stark) laws. For that reason, THE DARK REPORT will not devote much discussion to how the defense rebutted this count during the jury trial.

Willing To Indict

Many laboratory sales and marketing practices still in wide use today are described in the indictment. Even as the laboratory industry debates whether or not such practices are fully compliant with various federal regulations and laws, here's a real-world example where one U.S. Attorney viewed them as violations and believed this position was strong enough to prevail in court. The result was criminal indictments of three lab executives and a court trial.

To provide further insight and intelligence into this case, THE DARK REPORT interviewed the three defense attorneys. Their comments and conclusions are on pages 9-16. TDR

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Six Ex-IMPATH Officials Receive Their Sentences

Federal prosecutors close the books on one of the lab industry's biggest frauds

CEO SUMMARY: *Justice has been meted out to six individuals accused of criminal fraud in the Impath, Inc. case. During June, sentences were pronounced for former President and COO Richard P. Adelson and several other defendants. Adelson will serve 42 months in prison, pay a $1.2 million fine, and was directed to pay restitution totalling $50 million. The other defendants received lesser sentences.*

IN A COURTROOM IN NEW YORK CITY last June 13, 2006, four of the six defendants in the **IMPATH, Inc.** case received their sentences. The sentencing means that all of the original defendants have been convicted under federal criminal statutes.

The indictments of these six ex-employees of Impath were announced on March 30, 2005. As explained in the indictments, the defendants had conspired to manipulate the company's finances to produce as much as "$64 million in phantom revenue between the years 1999 and 2002."

When the fraud was discovered and became public knowledge in the summer of 2003, the company's stock price dropped 88%. Losses to investors approached $260 million. NASDAQ delisted the company and, on September 29, 2003, Impath filed a Chapter 11 bankruptcy action. *(See TDR, September 29, 2003.)*

First to be convicted was Impath's ex-Chairman and CEO, Anu Saad, Ph.D. On September 21, 2005, Saad dropped her not guilty plea and pled guilty to two counts of soliciting proxy statements containing false information and one count of "knowingly failing to implement a system of internal accounting controls."

Saad admitted that, in these proxy statements, she had failed to disclose compensation paid to her by Impath. These were personal expenses charged to an Impath corporate credit card and paid for by Impath. Totalling approximately $120,000, Saad had spent corporate funds for furniture, electronic equipment, beauty products, artwork, and personal travel.

No Accounting Controls

The second indictment was because Saad, as CEO, "knowingly failed to implement a system of internal accounting controls at Impath" that would have prevented the financial manipulation of Impath's actual revenues and other financial details.

Saad's sentencing came on January 17, 2006. She was given three months in prison, two years of supervised release, required to pay a $6,900 fine as well as a special assessment of

$300. Before her sentencing, Saad told the courtroom, "I just want to say how sorry I am for my conduct."

Saad's willingness to plead guilty to these three counts was probably a lucky decision, given the relatively light sentence she received. That's because of the sentence received by ex-President and COO Richard P. Adelson, who decided to fight his indictment and lost a jury trial.

Adelson found himself facing 12 counts. These included charges for conspiracy to commit securities fraud, to make false statements in SEC filings, and to falsify Impath's books and records. His trial commenced on January 30, 2006. It lasted two weeks and ended on February 16, 2006.

Convicted On Five Counts

The jury acquitted Adelson on seven counts, including two charges of soliciting a false proxy statement. But Adelson was convicted on the remaining five counts. His attorney announced that Adelson would file an appeal.

Adelson's sentencing was scheduled for May 30, 2006 and he faced the possibility of life in prison, given the maximum sentence possible.

At the sentencing, one reporter present wrote, "Weeping, an emotional Adelson apologized to the court and begged the judge for a more lenient sentence. 'Please allow me to continue to make a contribution,' Adelson said. 'I am asking your honor for a second chance.'"

He was also quoted in other news reports as saying "I have made some very serious mistakes and have failed miserably at my life's goals. I only blame myself and take full responsibility for that."

U.S. District Court Judge Jed Rakoff, who had also sentenced Anu Saad, noted that, while federal sentencing guidelines recommended a term of life in jail for Adelson, his crimes were not comparable "to the kinds of situations that have led to 20- and 25-year prison terms." This was a reference to the multi-billion dollar frauds, and subsequent convictions, in the **Enron**, **WorldCom** and similar cases.

Prison, Fine, Restitution

Adelson received a sentence of 42 months in prison, a $1.2 million fine, and an order to pay restitution of $50 million. Judge Rakoff acknowledged that Adelson would likely only pay a small portion of that restitution.

Just two weeks after Adelson's sentencing, it was time for the remaining four Impath defendants to receive their sentences. These individuals were: David J. Cammarata (former Chief Financial Officer), Peter Torres (former Vice President of Finance), Karin Gardner (former Controller), and Kenneth Jugan (former National Billing Director).

All Had Pled Guilty

All four had pled guilty to their indictments prior to the March 30, 2005 announcement by federal prosecutors of the indictments against Saad and Adelson. Because some were cooperating with the prosecution, their sentencing was scheduled to take place after the cases against Saad and Adelson had been adjudicated. The sentences were as follows:

Cammarata pled guilty to five counts. He was sentenced to one month in jail for each count, to be served concurrently, and five years of supervised release.

Torres pled guilty to four counts. He was credited with time served and put on three years of supervised release.

Gardner pled guilty to four counts. She received credit for time served and was given three years of supervised release.

Jugan pled guilty to three counts. He was credited with time served and received three years of supervised release.

SEC Injunctions

In parallel with federal prosecutors, the **Securities and Exchange Commission** (SEC) brought civil actions against these four individuals. On September 29, 2005, Cammarata, Torres, Gardner, and Jugan consented to permanent injunctions, including a lifetime ban on serving as an officer or director in a public company. Cammarata was also barred from appearing before the SEC as an accountant.

A seventh ex-Impath employee had agreed, in early 2005, to a civil settlement with the SEC. Former Impath Vice President Robert McKie, without admitting or denying SEC allegations, agreed to settle his case by paying a $150,000 penalty and returning about $100,000 in bonuses, with interest.

Financial Fraud Case

With the sentencing of all the Impath defendants, federal prosecutors closed the books on one of the more spectacular frauds ever to occur in the laboratory industry. The most useful lessons to be learned from the fraud at Impath are at least three.

First, corporate culture counts. It is not a coincidence that companies like **Procter & Gamble** and **Johnson & Johnson** are universally respected. Customers know when a company is doing the right thing.

Second, leaders must be capable and ethical. Good leadership is a major factor in business success.

Third, it is essential to have effective controls on management and operations. In the case of Impath, people with financial incentives had control or influence over the reporting of factors upon which their bonuses and incentives were based. TDR

Crime Doesn't Pay for Seven Ex-Impath Execs

NO ONE WILL EVER KNOW ALL THE REASONS that motivated seven managers to manipulate the financial statements of IMPATH, Inc. during the years 1999-2002. Here's a summary of criminal and civil actions that resulted from federal charges.

- **Anu Saad, Ph.D.** (former Chair and CEO): pled guilty to three counts. Sentence was three months in prison, two years of supervised release, $6,900 fine, $300 special assessment.
- **Richard P. Adelson** (fromer President and COO): jury trial, convicted on five counts, aquitted on seven counts. Filing an appeal. Sentence was 42 months in jail, $1.2 million fine, $50 million restitution.
- **David J. Cammarata** (former Chief Financial Officer): pled guilty to five counts. Sentence was one month in jail for each count, to be served concurrently, five years of supervised release.
- **Peter Torres** (former Vice President of Finance): pled guilty to four counts. Credit for time served, three years of supervised release.
- **Karin Gardner** (former Controller): pled guilty to four counts. Credit for time served, three years of supervised release.
- **Kenneth Jugan** (former National Billing Director): pled guilty to three counts. Credited with time served, three years of supervised release.
- **Robert McKie** (former Vice President): civil settlement with the SEC, without admitting or denying SEC allegations, paid $150,000 penalty and returned about $100,000 in bonuses, with interest.

In SEC civil actions, Cammarata, Torres, Gardner, and Jugan consented to permanent injunctions, including a lifetime ban on serving as an officer or director in any public company.

CEO SUMMARY:* *This was the first criminal case involving anti-kickback violations brought against executives of a public laboratory company. Federal prosecutors charged the defendants with offering inducements to referring physicians in several ways. Defense counsel rebutted the prosecution's case, using several arguments that many laboratory compliance experts would consider both novel and unlikely. This story expands upon the information presented on pages 2-5 of this issue.

ACQUITTAL FOR THREE DEFENDANTS

Defense Attorneys Discuss Details Of UroCor Jury Trial

FOR MANY YEARS TO COME, the criminal indictments, trial arguments, and jury decision in the case of three ex-**UroCor, Inc.** executives will surely cause consternation and compliance headaches for lawyers, pathologists, and laboratory managers.

That's because there are no winners in this unusual laboratory compliance case. For the three defendants, their victory in court may be a satisfying vindication, but it comes only after several years of legal fees, emotional stress, and loss of professional reputation. Those years and the expenses incurred can never be reclaimed.

For the U.S. Attorney who investigated the case and decided to indict, the jury's acquittal of the three defendants represents a setback in the efforts of the **Department of Justice** to enforce Medicare anti-kickback laws. Had a conviction resulted, it would have sent a message about what can happen to those who operate their businesses in violation of the law.

Laboratory Compliance

For pathologists and laboratory managers, this trial's outcome only makes anti-kickback compliance more difficult. They must consider the experience of this jury trial, which is not binding anywhere, but demonstrates that federal healthcare prosecutors may file charges in similar situations.

At the same time, the trial's outcome can be psychologically reassuring to referring physicians. After all, they have a jury verdict in a court case that says deeply-discounted pricing in client-billing arrangements doesn't trigger inducement that would violate anti-kickback law. This layman's view, if not informed by other compliance issues and opinions, has the potential to encourage physicians to play one laboratory competitor against the other in order to get the lowest discounted test prices.

And what about lawyers who provide guidance to clinical laboratories and pathology group practices on Medicare and Medicaid compliance? The trial's outcome leaves them with neither a clear conclusion nor useful guidance as to how federal prosecutors might file future actions that claim labs or pathology groups have violated anti-kickback laws in their arrangements with referring physicians.

Into this situation, THE DARK REPORT can provide some exclusive intelligence. In the following pages, attorneys for the defendants share their insights and the arguments they used to convince the jury to acquit the three defendants on all counts.

THE DARK REPORT has organized this information to provide a discussion of each relevant point. However, because of the variety of issues, and the complexity of the arguments provided by prosecution and defense during the case, the comments on the following pages can only summarize a few of the more interesting points argued during the trial.

Setback For the Feds

What will surprise those who have studied laboratory compliance in great detail is how the defendants' attorneys developed a defense that flaunts the popular wisdom. One simplistic way to explain this is to say that the defense argued: 1) that everything done by the defendants while working at UroCor was legal; 2) that what UroCor did in the marketplace was comparable with identical practices at competing laboratories; and, 3) that, among all the documents, statements, and pronouncements in the public record during the time of the alleged crimes, the government itself had acknowledged these activities as widespread and not in violation of then-current laws.

It should also be noted that the attorneys in this case are active litigators. Their job is to defend their client and gain acquittal. Therefore, they will analyze the law in a different way from attorneys who practice general corporate law, for they need to present their client's position in a way that refutes the prosecution's accusations. Thus, the strategies and tactics used in this trial will be unorthodox for those who are experts in laboratory compliance and seldom litigate in court.

Proving "Specific Intent"

Reid Robison was the attorney who represented former UroCor Chairman, President and CEO William Hagstrom. "To convict someone of a violation of Medicare anti-kickback law, the prosecution must prove 'specific intent' by the defendant," stated Robison, who practices at **McAfee & Taft** in Oklahoma City, Oklahoma. "This means that the government must prove, beyond reasonable doubt, that the defendant knew what he was doing was a crime, and, with this knowledge, then acted with intent to induce referrals because of remuneration—the kickback—he paid to the referring provider.

"Under the anti-kickback statute, these two defendants could not be convicted unless they knew that what they were doing was a crime and they then acted with this knowledge," continued Robison. "For the prosecution to win a conviction, it would have to convince the jury of two things. First, that the actions taken by UroCor in the marketplace caused the payment of illegal inducements to referring physicians—inducements that were illegal under the Medicare anti-kickback statute. Second, that the two defendants acted with the knowledge that these practices were illegal."

What Defendants Believed

"At the end of the day, our defense was essentially based upon the mental state of the defendants—that they believed their actions were legal," noted Michael J. Barta of **Baker Botts** in Washington, D.C. He was the defense attorney for Mark G. Dimitroff, former Vice President of Sales and Marketing at UroCor.

"On this point, we emphasized the rulings in two prior court cases involving the Medicare anti-kickback law," added Barta. "One was the 1985 case of *United States v. Greber*. The other was the Hanlester ruling by the 9th Circuit Court of Appeals in 1995. These two cases teach that you must have intent and you must conspire to break the law."

"The second basic defense we offered was that the business practices at UroCor not only did not violate the law, but were recognized in public government statements as widespread and within legal bounds," said Robison. "Our contention was that, in the years 1993 to 1998, the government's theory on discounted lab test pricing as an inducement had never been announced and that its appearance in this indictment was a novel theory."

Facts And Evidence

Hagstrom and Dimitroff's attorneys did not contest the facts and the evidence presented by the prosecution that UroCor offered discounted prices that were below the laboratory's cost. They also did not contest the fact that UroCor evaluated the referring physician's specimen volumes and payer mix to determine if the volume of Medicare business could financially offset the highly-discounted pricing extended to the physician.

"Our argument was 'so what,' because the U.S. government, in a series of pronouncements, had made clear that essentially all labs were discounting and they were discounting below cost, and that it was profitable only because of the Medicare business," observed Barta.

"Given that the government knew that, what had it said?" asked Barta. "Pronouncements of the U.S. govern-

Digging Deep Into Documents Bolsters Defense

IN LOOKING TO COUNTER PROSECUTION ARGUMENTS, the attorneys for the three ex-UroCor defendants did extensive research into all the public statements, papers and opinions made by government healthcare officials.

In count one of the indictment, paragraph 23 states "UroCor consistently billed Medicare the Company's standard list price for a laboratory test, even when the referring doctor received a "special price" for that particular test for his non-Medicare patients. The effect of the "special pricing" *was that no discounts were given to Medicare patients, and UroCor did not inform Medicare of the discounts provided to non-Medicare patients*." *(Italics added by THE DARK REPORT.)*

"Much of the government's case was organized around this point that UroCor gave discounts to physicians and didn't lower its prices to Medicare," stated Michael Barta, attorney for the defense. "To rebut this claim, we entered two government documents into the case."

First was a letter from the **Department of Health and Human Services** (HHS) to the **American Association of Bioanalysts**, written in January 1985 and labeled FQA-422. Its key statement is, "There is no prohibition against a laboratory charging a physician less for non-Medicare patients than the amount it would be paid under the fee schedule provisions of the Deficit Reduction Act of 1984."

The second document is Exhibit B of the Plea Bargain between the United States and Robert E. Draper, defendant. It was a part of the case against National Health Laboratories, Inc. and this document was filed in court on December 18, 1992. In the "Stipulated Statement of Facts," the government writes: Laboratories have adopted a practice of discounting the prices they offer physicians. Because laboratory prices to physicians are unregulated, *it is not illegal for a laboratory to charge a physician a price that is less than the price charged to patients or to third party insurers. Laboratories engage in harsh price competition and often offer extremely low prices to physicians in order to obtain their accounts*." *(Italics added by THE DARK REPORT.)*

ment said that discounting is a problem if, and only if, the lab discounts below fair market value.

"Once we made this point, the argument in court shifted to the definition of market value," he continued. "The language that was relevant and guiding for our case was the government's use of the term 'fair market value' in public statements. These government statements said nothing about pricing 'below cost.'

Definition Of Market Value

"Having made that point during the trial, we next addressed the definition of market value," he continued. "Our response was simple. Market value is set by the competition. If the price UroCor charged was essentially the same as competing laboratories, then on what other basis might the physician choose one (equally-priced) laboratory over another? Our answer was quality! Moreover, government statements in the public domain make it clear that much of the Medicare regulations and statutes have the intent to encourage providers to base their buying decisions on quality."

Robison echoed Barta's comments. "We thought it was absolutely crystal clear, in the government's own pronouncements, that pricing to meet competition, and pricing to meet market value, was understood by the government to be the 'then current' practice in the lab industry and was accepted by the government," he said.

"Under the anti-kickback statute, it is not an inducement if the price is at the market rate and the doctor can get the same price from other labs," added Robison. "That makes price a tie between competing labs. There is no inducement there! Now the doctor must pick the laboratory on the basis of quality—and that's the position the government said it wanted to maintain. And that's exactly what these managers at UroCor did. They made it possible for a doctor to choose a lab on the basis of quality.

"There's no inducement in this situation," declared Robison. "The doctor is not getting anything from UroCor that is not available to him from other laboratories. And that's the point we emphasized in court. UroCor's decision to discount was in response to competition."

Counter To Popular Wisdom

The subtlety of these arguments runs contrary to the popular wisdom about compliance during the 1990s. Popular wisdom said that discounted pricing and client bill arrangements had the potential to create illegal inducements. The physician could make money by marking up the discount-priced lab tests and billing private payers and patients. Meanwhile, the laboratory billed Medicare for full reimbursement (and used those funds to offset losses incurred from the discounted pricing). Under certain circumstances, these types of arrangements might trigger inducements considered illegal by the Medicare anti-kickback law.

The defendants made an argument that goes in an entirely different direction. "How can a deeply-discounted price be an inducement, if competing laboratories are offering the same physician comparable pricing?" goes the argument. "Since the physician can get the same price from several labs, there is no inducement. Instead, the physician must base his decision on other factors, like better quality and service. And, that is precisely what Medicare statutes want to encourage."

Compliance Changes

Barta did acknowledge that some government positions on these points have changed in recent years. "OIG Advisory Opinion 99-13, posted on December 7, 1999, does describe price discounting arrangements that could trigger anti-kickback violations," he commented. "This fraud alert represented a new federal perspective on this issue. However, my client had left UroCor in the months prior to its issuance and so the shifting stance expressed in Advisory Opinion 99-13 did not play a role in this trial."

Federal prosecutors argued that remuneration existed when UroCor gave a doctor a discounted price and that doctor turned around and marked up that same test when she billed private payers. "To support these arguments, prosecutors presented some nicely-designed charts in court," recalled Barta. "They showed how UroCor would sell a test to the doctor at, say $3. The doctor would then submit a claim to Blue Cross, for example, for $59 and pocket the $56 difference.

Two Distinct Price Markets

"We argued that those types of transactions were irrelevant to the anti-kickback accusations," he noted. "We pointed out that there were two distinctive pricing markets. One pricing market was 'retail,' the price that payers, whether private or Medicare/Medicaid, would reimburse claims," explained Barta. "The other was 'wholesale,' the price that competing laboratories would sell lab tests to the physician.

"We countered the government's argument by saying that doctors were free to do what they wanted with the discounted tests," he said. "Many times, doctors might not bill either the payer or the patient for the lab test. In that case, they wrote off the $3 dollar cost.

"Alternatively, some physicians would mark up the test, submit the claim, and make money," noted Barta. "Whether the doctor did or did not mark up the test was irrelevant to UroCor. It could only gain a doctor's business by offering prices comparable with the competition, and that's what set market value in this wholesale market. The jury apparently accepted this position.

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"From a broader perspective, the government tried to sell its case as one based on 'discrimination'—that it was wrongful for the defendants to offer discounts to doctors without offering these same discounts to Medicare," noted Barta. "The judge expressly rejected this position and prohibited the government from making this argument to the jury."

Doctors As Consultants

In the count involving anti-kickback violations, it was claimed that UroCor violated the law because it entered into consulting service contracts with physicians, in some cases paying individual doctors as much as $76,000 per year. But it had no reports filed by these doctors to indicate they performed work in return for this compensation.

"In court, we demonstrated that these doctors had done this work," recalled Barta. "The documentation existed. But it was not found in the sales or marketing records because these consulting service contracts originated in the research arm of UroCor.

"UroCor was devoting extensive resources—money and people—into investigating new disease markers, potential therapies, and doing basic science," he continued. "UroCor researchers were contracting with client physicians who could provide specific types of specimens needed for this research. They were also transmitting outcomes and follow-up information on the patient over time.

"In court, these facts prevailed and it became clear that the consulting services agreements UroCor signed with physicians did represent payment for valuable services rendered," summarized Barta.

Waiving HMO Charges

There was a significant part of the government's anti-kickback case which never made it to the court case. In the indictment, under count one dealing with violations of the anti-kickback law, the government had described UroCor's use of insurance reimbursement assessments (IRAs).

Between 1992 and 1999, UroCor used IRA arrangements in situations where it did not hold managed care contracts. These IRA agreements spelled out how, for a 90- to 180-day period while UroCor was negotiating a contract with the managed care company, it would accept whatever out-of-network reimbursement it might be paid and would not pursue payment directly from patients or physicians.

In the indictment, prosecutors described this arrangement as creating illegal inducement between UroCor

Securities Issues Linked to UroCor's Fast Growth

COUNT TWO IN THE TRIAL of the ex-UroCor executives involved "conspiracy to commit securities fraud in violation of Title 18, United States Code, Section 371."

"There was some complex interplay across both counts during the trial," said Kevin Krahl, attorney for Michael N. McDonald, former CFO for UroCor. "Essentially, federal prosecutors were claiming that UroCor's business was growing through illegal means and that affected the accounting.

"However, we had a good rebuttal for the prosecution's arguments," continued Krahl, who is a partner at **Hornbeek Krahl Vitali & Braun** in Oklahoma City, Oklahoma. "For example, with the IRA agreements, the bad debt reserve was always higher than the total balance generated by the IRA accounts. And, in fact, collections averaged about one-third of the balance, so this was conservative accounting.

"Another weakness in the prosecution's case was their lack of understanding accepted accounting standards," recalled Krahl. "We demonstrated that our accounting standards were strict and consistent with professional standards.

"Further, allegations of securities fraud did not stand up to scrutiny, since no shareholders were on record as having lost money," added Krahl. "In fact, during the years involved in this case, Urocor shares performed acceptably well."

because it created remuneration. That remuneration was the time saved by the physician and his office staff because they could send all their specimens to one laboratory.

"We argued that this was not remuneration as defined in the statute," recalled Barta. "The statute defines remuneration as cash or value in kind. Saving time does not meet this definition and the judge accepted our argument.

Using OIG Fraud Alerts

"Further, we offered into evidence that the basic practice of waiving charges to managed care patients, as UroCor was accused of doing, was recognized by the government as allowable," he explained. "The evidence was the fraud alert published on December 19, 1994 by the **Office of Inspector General** (OIG). It discusses "Waiver of Charges to Managed Care Patients and says it is acceptable to waive lab testing charges if no remuneration, including managed care contract utilization incentives, is paid to the doctor." *(See TDR, August 26, 2002.)*

"These points were all argued during pre-trial motions and hearings," added Barta. "The judge threw out the section of the indictment that involved the IRAs and that issue was never part of the actual trial."

Issue About Test Prices

On the claim by prosecutors that UroCor offered prices to physicians that it did not give to Medicare, the defense offered some interesting points. "The government postured its case on the fact that UroCor was offering discounted prices for lab tests to referring physicians, but UroCor did not give these same lab test prices to Medicare," noted Barta.

"Our contention was that, not only was this not illegal, but the practice was widespread in the laboratory industry and pronouncements by the United States government acknowledged these and other practices," he continued. "We offered several documents that demonstrated government statements on this point. For example, in the 1992 case between **National**

Health Laboratories, Inc. (NHL) and the federal government, NHL's President and CEO, Robert E. Draper, pleaded guilty to two counts of submitting false claims. In the stipulated statement of facts, the government stated that it is not illegal to offer clients a discount price that is less than Medicare."

"Another document that we used was a 1985 letter from the **Department of Health and Human Services** (HHS) that was responding to a request for guidance," said Barta. "It stated that there was no prohibition against a laboratory charging a physician less for non-Medicare patients than the Medicare fee schedule." *(See sidebar on page 12.)*

The comments on these pages cover some of the more interesting and relevant points in the UroCor case, but only from the perspective of the defense. Since the jury voted to acquit all three defendants on all counts, the arguments used by the defense are worthy of study.

> ***That is one reason why the practical lessons to be learned from this case are limited. In one sense, this might be considered a "time capsule" case. Today's compliance environment has important differences from that of the 1990s.***

Because of the complexity of this subject, and the volumes of information presented before and during the trial, it is impossible for THE DARK REPORT to present a more comprehensive and detailed review of the UroCor anti-kickback and securities fraud case. That is a job more properly left to experts in compliance and law—individuals with the training and experience to comment on the full range of implications in each argument offered by prosecution and defense. However, it is unlikely that such a review will ever be conducted, or if it is, that its findings would be made available to pathologists, lab managers, and their legal counsel.

For that reason, THE DARK REPORT considered this to be an important opportunity to publicize certain aspects of this case. By allowing the defense attorneys to comment on their legal strategies and how they responded to various government claims of illegal business practices, it gives the laboratory industry valuable perspectives about this unique case.

An Important Caveat

Readers are urged to also keep an important point in mind when reviewing the information presented on these pages. The UroCor anti-kickback case involved sales and marketing programs conducted from about 1990 through 1999. Both prosecution and defense were arguing their positions based on industry practices and government statutes and guidance that were relevant to that time period.

That is one reason why the practical lessons to be learned from this case are limited. In one sense, this might be considered a "time capsule" case. Today's compliance environment has important differences from that of the 1990s.

Finally, the defense attorneys also had advice to share with laboratories and pathology group practices about how to structure their compliance programs and how to use legal counsel to best effect. Coming issues of THE DARK REPORT will present their recommendations. **TDR**

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Anatomic Path Trends

"In-Office Pathology Mini-Labs" Offered by Physician GPOs

GPOs contracted with a turn-key resource to help physicians build their own pathology laboratory

EARLIER THIS MONTH, two large physician GPOs (group purchasing organizations) announced that they had signed national agreements with a company that would "provide in-office pathology laboratories to their gastroenterology, urology, and dermatology member physicians."

The pathology company is the **Twincrest Group** of Cleveland, Ohio. The GPOs are **International Gastroenterology Network** (IGN) and **International Urology Network** (IUN). These groups are part of **International Physician Networks** (IPN), a specialty group subsidiary of **Americasource-Bergen Corporation** of Chesterbrook, Pennsylvania. The company is a pharmaceutical distributor and provides a variety of logistical services to hospitals, pharmacies, physicians, and other types of healthcare providers.

Help with Pathology Labs

"Our partnership with TwinCrest assists us in accomplishing a key objective for our members," stated Tom O'Rorke, Director, Sales and Marketing of IPN. "Practices that utilize the TwinCrest program can expect improved productivity and a higher standard of patient care while at the same time realizing a new revenue stream for their practice...[It will] help our practices defray the increasing expenses of running a practice today."

The national agreement between Twincrest Group and these two specialty physician networks is the latest sign of the serious interest that gastroenterologists and urologists have for anatomic pathology services. Moreover, GPOs tend to sign contracts with vendors whose services are in high demand by GPO members. So it is likely that these new contracts between Twincrest and the IGN and IUN GPOs were in response to the interest shown by their physician members in establishing in-house anatomic pathology laboratories.

Twincrest Group will help member physicians of the two GPOs design, build, and operate their own pathology laboratories. Twincrest Group will also assist specialist physician groups contract for professional services with pathologists. Twincrest has already established these types of relationships for physician clients in Ohio and New Jersey.

The national agreements between Twincrest Group, IGN, and IUN have the potential to involve many gastroenterology and urology groups. IGN says it has 1,000 physician members. IUN claims to have 4,500 physician members.

Pathologists and practice administrators should take note of this new development. It has the potential to place additional pressure on local pathology groups as their long-time gastroenterology and urology clients establish in-house pathology labs. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There's a new crop of Web-based, direct-to-consumer laboratory companies. In recent months, Joplin-Missouri-based **MyMedLab, Inc.,** (*www.mymedlab.com*) and **MedLabUSA, LLC** of Tampa Florida (*www.medlabusa.com*) have begun to seek publicity. Both companies offer patients a way to order laboratory tests directly via the Internet and both companies contract with other laboratories to perform the testing.

MORE ON: Internet Labs

It was in the late 1990s, during the dot.com boom, that several direct-to-consumer, Web-based laboratory companies surfaced with similar marketing tactics and a business strategy of buying lab tests from existing lab companies. After attracting a fair amount of interest and notice within the laboratory community, each withered from lack of business and was eventually closed. Even today, direct-to-consumer lab testing remains a tiny part of the overall market.

MICROBIOLOGY BREAKTHROUGH: GAS-FREE BEANS!

Here's good news from the world of microbiology. Researchers have discovered two strains of bacteria which can be added to beans and which will reduce the flatulence created as the beans move through the digestive tract. Marisela Granito and her team from **Simon Bolivar University** in Caracas, Venezuela published their findings in the *Journal of Science in Food and Agriculture*. For years, cooks have fermented black beans before cooking to reduce the gas produced by the beans. Granito and her team identified *Lactobacillus casei* and *Lactobacillus plantarum* as the main contributors to this effect, because they decrease the soluble fiber content by more than 60% and lower levels of raffinose (known as a cause of gas) by 88%. They also learned that the nutritional value of the beans is maintained.

ADD TO: Gas-Free Beans

Commercial food processors may use Garnito's discovery to produce "low gas" beans for consumers. Similar gas-free beans are being grown and sold in the United Kingdom. Developed by noted anthropologist Dr. Colin Leaky, his new variety of the manteca bean is flatulence-free and now sold commercially. In the 1960s, while Leaky was working in Uganda, he observed that mothers were hesitant to feed beans to their children because colic would often result. Motivated to restore this source of protein to the local diet, Leaky worked for decades to develop a form of flatulence-free beans that can be grown in the United Kingdom's climate. The product is sold under the name "Prim Beans" and it's believed that tannins in the seed coat play a role in reducing the gas produced during digestion.

PROXYMED'S NEW NAME

ProxyMed, Inc. has a new name. In recent months, the company has adopted the name **MedAvant Healthcare Solutions**. It provides services in physician office connectivity. In 1999, ProxyMed acquired **Key Communications Systems, Inc.**, which provides remote printing solutions for labs.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 14, 2006.

THE DARK REPORT

UPCOMING...

- *Lessons Learned: Defense Attorneys in the UroCor Anti-Kickback Case Offer Important Compliance Recommendations.*
- *Integrated Health System Becomes Acquirer/Manager of Other Hospital Labs.*
- *Supreme Court Refuses to Rule in LabCorp's Molecular Patent Appeal: Ramifications for Laboratory Industry.*

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