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Fueled by several billion-dollar-plus acquisitions by leaders in the imaging sector, the convergence of in vitro diagnostics, in vivo imaging and information technology is the biggest story surrounding these sectors in 2007. The acquisitions of the Bayer Diagnostics (Tarrytown, New York) business of Bayer Healthcare and of Diagnostic Products Corp. (Los Angeles) by Siemens Medical Solutions (Erlangen, Germany) and Abbott’s (Abbott Park, Illinois) clinical diagnostics and point-of-care testing businesses by GE Healthcare (Little Chalfont, UK) are transformational transactions.

The combinations, the first of their kind within the medical products industry, are representative of emerging concepts about the benefits of integrating imaging and in vitro diagnostic test information. The new Siemens and GE businesses will add information technology to the mix, an increasingly important aspect of both imaging and laboratory testing.

The clinical diagnostics market continues to expand, and may be entering a new growth phase as the value of diagnostic test data increases due to its integration with imaging data and advances in related information technology. The new convergent strategies could prove to be well-aligned with the emerging requirements of the market, addressing needs for integration of technologies, increasing the role of information technology in diagnosis and monitoring, and moving toward a systems-based approach to healthcare. The strategy also significantly expands the market addressed by the companies. The combined worldwide market for diagnostic imaging equipment and in vitro diagnostic products totaled about $66 billion in 2005, with imaging products accounting for 56% of the total.

Also impacting the importance of diagnostics within the healthcare system is the continuing emergence of personalized medicine, with technologies such as nucleic acid diagnostics and proteomics playing a key role in market expansion. Developments in areas such as pharmacogenetic testing, genetic screening, cancer diagnostics and cardiac marker testing are expected to fuel additional growth in the sector, and likely result in the clinical laboratory playing a central role in the management of patient data.

While the increasing importance of information technology in clinical diagnostics has been recognized for some time by major suppliers in the IVD industry, the Siemens and GE acquisitions represent the first time that companies will combine both a major supplier of diagnostic products and clinical information systems along with imaging equipment under one roof. Experts presenting on global trends in healthcare at the July 2006 annual conference of the American Association for Clinical Chemistry (AACC; Washington) provided support for the premise that transformational changes are occurring in the market that may require new business models to be implemented by suppliers and providers. As discussed by Carolyn Kovac, PhD, of IBM (Somers, New York), at the meeting, a number of factors – including changing demographics, new economic models for healthcare delivery, technical
innovation and globalization – are converging to create a tipping point that will transform the market, threatening some business models but also creating new opportunities. Kovac said she expects a new healthcare information network to be developed that will have many of the elements of today’s financial networks, such as point-of-care accessibility and direct access by individuals, as well as greatly enhanced capabilities to improve the accuracy of diagnostic and treatment decisions. The beginnings of a National Health Information Network already are in place, having been implemented mainly in academic settings for clinical genomics applications.

Kovac believes existing separate networks that have been established for specific applications, such as biobanks focused on cancer and genetic data in countries such as Sweden, Singapore, Japan and the U.S., eventually will be tied together to create national and perhaps global health information networks, again in analogy with existing financial networks. Another example is computer grids, such as the National Digital Mammography Network Archive in the U.S., which can be expanded and interconnected to form the basis for a national health information network. Medical imaging, in fact, is likely to be one of the first segments of the market to develop such information networks.

A key benefit of implementing health information networks and expanding the use of informatics in medicine is likely to be improved quality in health care. As discussed by Harvey Fineberg, MD, PhD, president of the Institute of Medicine (Washington) at the opening AACC plenary session, there is a significant need for improvement, since at present 11% of patients potentially receive harmful, rather than beneficial, healthcare. Studies cited by Fineberg conducted in New York State, Colorado and Utah indicate that between 53% and 58% of all injuries due to healthcare errors are preventable. Technology, and particularly information technology, will play a significant role in improving healthcare quality, but implementation of improved systems that are less complex, more reliable, and less error-prone also will be a key factor. Clearly, laboratories cannot solve all of the problems of the healthcare system on their own, which leads to a need for integration

At the March 2007 edition of the UCI Health Care Forecast Conference, held annually by the University of California Irvine’s Graduate School of Management, Arnold Milstein, MD, MPH, chief physician for Mercer Human Resource Consulting (New York) and medical director of the Pacific Business Group on Health (San Francisco), said that the main focus of efforts for improving efficiency should be, at least initially, on the sickest 20% of patients who account for about 60% of spending. One approach to better efficiency, comprised of strategies already implemented and validated by leading experts in process efficiency, is the ambulatory ICU, which focuses on improved structures for delivery of primary care to the sickest 20%. The overall strategy – with diagnostics and imaging heavily involved – involves a greater reliance on disease self-management enabled by economical relationship-based coaching, coupled with lean primary care MD visits, and referral to the most cost-effective specialists and hospitals.

While the cost of implementing and managing such a strategy would increase spending by 13%, the savings from improved efficiency at all levels is estimated at 48%, and results in 35% lower net spending. That strategy includes use of new technologies such as remote monitoring to assist patients in compliance with self-improvement plans. Significant improvements in efficiency for management of the sickest 20% of patients – based on a projected 35% savings for that population – would produce a 20% reduction in total healthcare spending.
About the book

This sourcebook focuses on the key areas of interest and importance for technology developers and companies as they look to the future. Advances in Diagnostics & Imaging, Vol. 2 represents the second such collection of information – some 300 pages of it – put together by the staff of the only daily newspaper serving the industry. Medical Device Daily, which is part of the BioWorld group of publications produced by AHC Media LLC, is the only daily newspaper cover the med-tech industry. And Diagnostics & Imaging Week is a weekly compilation of news impacting both the clinical diagnostics and diagnostic imaging sectors. On the pages that follow, you’ll find overviews of those areas we have judged to be of the most interest moving forward. Beginning with a look at some of the associations that serve those medical sectors, we then take a look at the “three R’s” – regulatory, reimbursement and research – that reflect both what has happened and what may be on the horizon insofar as activities by those branches of government that impact the diagnostics and imaging sectors are concerned. Our “Deals” and “Financings” chapters highlight key occurrences in mergers-and-acquisitions activity and in fundraising in the period from roughly July 2006 through April 2007. In “A Look Ahead,” we take just that – a view of where the respective sectors are headed – in particular the clinical diagnostics side, which is riding a long and large wave of change. That wraps up the Overview section of the book.

Following that section is what many might regard as the heart of our look at these industries – about 175 pages devoted to 10 chapters ranging from “HIV/AIDS Testing” to “Emerging Companies and Sectors.” In each of these chapters, we take a broad look at some of the key developments – and companies – shaping that particular segment. Those overviews are followed by smaller stories, usually focused on single companies or developments, which add illumination to what is happening in those fields.

Let me note that this book is not intended to be a directory, so we have not sought to identify and include every company and technology from among the hundreds – even thousands – involved in these sectors. What we have attempted to do is to make note of sector leaders, while also weaving in promising companies or promising areas of development that we’ll hear more about in the future.

This book resulted from substantial efforts of the staff that brings you Medical Device Daily, along with Diagnostics & Imaging Week and Medical Technology & Devices Week and our two monthlies, Biomedical Business & Technology and Cardiovascular Device Update. I especially want to cite the work of Executive Editor Don Long, Managing Editor Holland Johnson, Senior Production Editor Rob Kimball, Staff Writers Karen Young and Amanda Pedersen and Washington Editor Mark McCarty in gathering the materials included in this book. Special thanks to Staff Writer Karen Young, who focuses on the clinical diagnostics and imaging areas for MDD and D&IW, and Contributing Writer Michael Simonsen, PhD, who is our lead contributor in the clinical diagnostics area. Their efforts are greatly appreciated.

As always, my thanks to you as well for your interest in this book and our other publications.

– Jim Stommen, National Editor
FDA to push ahead with assay guidance despite opposition

By MARK McCARTY
*Medical Device Daily* Washington Editor
and KAREN YOUNG
*Medical Device Daily* Staff Writer

Makers of *in vitro* diagnostics for in-house use have faced little FDA oversight in the past, and despite the existence of regulations, the Centers for Medicare & Medicaid Services (CMS; Baltimore) has written CLIA standards covering this sector.

Nevertheless, the FDA published guidance last year for *in vitro* diagnostic multivariate index assays (IVDMIAs or MIAs).

According to the draft guidance, much of the agency’s concern was based on the notion that MIAs are not among the “common elements of in-house tests” and because of the complexity of these high-tech assays, the FDA is seeing more reasons to be concerned about safety and effectiveness.

At a meeting on the topic in February 2007, the agency admitted that the current guidance, when overlaid on the 1997 guidance for analyte-specific reagents (ASRs), has created some confusion. The FDA is motivated by a proliferation of assays thanks to the surge in interest in personalized medicine, especially since modern assays often employ algorithms used by computer software, which the agency has asserted jurisdiction over in a wide range of devices. Up to now, the agency has seen many assays as a “very narrow niche of devices” that have benefited from the regulatory discretion that the agency has heretofore exercised.

Courtney Harper, PhD, lead biologist at the Division of Chemistry and Toxicology Devices at the Office of In-Vitro Diagnostics, insisted that despite the reagent guidance, clinical labs that develop in-house tests are “acting as manufacturers of medical devices and are subject to FDA jurisdiction.” The rationale here is that the reagent guidance does not “actually extend to the tests that use” those reagents.

However, the first draft of the MIA guidance probably generated as much confusion as it resolved.

“We realized after we published the guidance that a lot of the questions that we had been hearing have been related to clarification of the definition” of a device, Harper said, adding that a device can use an algorithm similar to those commonly employed in MIAs to detect protein structure and not qualify as a device, as an example. “We would like to see comment from the public on the definition” of a device for this class of assays, she noted.

Paul Redensky, a partner in the Miami office of McDermott, Will & Emery (Chicago), said that the guidance has “raised a large number of issues, including . . . FDA’s authority” to regulate these assays. However, he focused on “questions that laboratories need to have answered,” which include the definition of an MIA and which elements within a lab’s operation are subject to FDA regulations. Other issues, he noted, include how the quality system regulations (QSRs) mesh with the Clinical Laboratory Improvement Amendments (CLIA) standards, which are overseen by the CMS.

“Those who fund research . . . will not find it acceptable to find out late [in the development process] that the FDA issued a guidance document” that will impose a new regulatory burden,” Redensky
observed.

He said that one area of ambiguity is that of the difference between a prognostic claim and a predictive claim with respect to a given assay. "Generally, we will have a claim that is talking about the likelihood of some outcome," with survival of a disease vs. the recurrence of a disease as an example. "These things are key because" the answer to that question plays a large role in whether the device is eligible for a 510(k) filing, which is vital information when lining up finances.

Richard Samp, chief counsel with the Washington Legal Foundation (WLF; Washington), said that he is "convinced that any attempt by FDA to impose significant regulation on laboratory-developed tests will be a setback for public health" and is "contrary to law."

Samp commented that the Sept. 28, 2006, citizen petition filed by WLF requested that the agency avoid imposing regulations on assays for in-house use, which he said "are developed by the thousands each year," and that "there is no evidence that LDTs [lab-developed tests] are inaccurate." Because of CLIA, "it is difficult to understand why FDA wants to fix" a system that is not broken. Samp further charged that the guidance would "have a crippling effect" on availability of LDTs.

Thomas Tsakeris, president of the Coalition for 21st Century Medicine (Arlington, Virginia), indicated that the coalition "is concerned that in its current form, the draft guidance will have adverse, unintended consequences," including impedance of innovation and preclusion of improvements to current MIAs. He said that the effort to get up to speed on the quality systems regulations "could take years, would be prohibitively costly, and would drive up healthcare costs." He also said that the guidance would create reimbursement problems and potentially discourage future investment.

Carolyn Jones, vice president for technology and regulatory affairs at the Advanced Medical Technology Association (AdvaMed; Washington), said that the association "represents a diverse group of interests" and that "the vast majority of AdvaMed's membership has concluded that laboratory-developed tests . . . meet the definition of a medical device and should be subject to a reasonable risk-based approach."

However, Jones also said that AdvaMed members "believe the process would have been better served if FDA had issued a concept paper and held a public meeting before issuing the guidance."

"The clinical lab community does not understand which types of medical algorithms that FDA intends to regulate," Jones said, adding that because some algorithms have been in use for an extended period of time, "FDA should provide more detailed information on which products would be subject to regulation."

Daniel Schultz, director of the FDA's Center for Devices and Regulatory Health (CDRH), said at the end of the meeting that "we're on the cusp of a fundamental change in how medicine is practiced" thanks in part to diagnostics. He pointed out that the "divergent opinions regarding the scope of the guidance," suggested that FDA "may not be able to satisfy everyone."

The FDA needs to "do a better job of associating technology with risk," he said, a reference to comments that the proposal seems to operate more from a technological innovation standpoint rather than a risk-based approach, but Schultz nonetheless insisted that there is a very real "link between the changes in technology and the level of risk."

"The idea that we can simply go back to where we were several months ago . . . is unacceptable," Schultz noted, but promised that the guidance will "not be the last piece of this discussion."

At the time of issuance of the draft regulatory guidance regarding so-called IVDmia in September
2006, an FDA spokesman wrote in an e-mail to Medical Device Daily that the agency believes there is a “relatively small but growing number of tests in this area.” And, judging from the guidance, manufacturers might be required more often to seek a 510(k) or pre-market approval (PMA) for its diagnostic tests.

“Regulation is always risk-based and so whether a 510(k) or a PMA for these devices [would be necessary] would depend on intended uses and risk profiles,” the spokesman wrote.

The agency also noted it expected the new guidance to help ease any public concerns that such tests are safe and effective.

“More and more of these kinds of medical tests are being made available each year,” said CDRH’s Schultz. “It is important for the companies and labs making the tests to clearly understand the regulatory requirements in place so that the tests they develop are as safe and effective as possible.”

In the draft guidance, the agency noted that “FDA is aware of some confusion about the regulation of IVDMIAs that are developed by, and used in, a laboratory. We believe this confusion derives in part from FDA’s approach to regulation of laboratory-developed tests that use commercially available [analyte-specific reagents] and other commercially available, FDA-regulated components.”

Some of that confusion, the FDA acknowledged, comes as a result of the agency’s ASR rule, which does not extend to tests developed in-house, or so-called “home-brew” tests developed by and used only in a particular laboratory.

Accordingly, the agency also issued guidance on ASRs in the form of “frequently asked questions.”

The guidance defines IVDMIAs as “test systems that employ data, derived in part from one or more in vitro assays, and an algorithm that usually, but not necessarily, runs on software to generate a result that diagnoses a disease or condition or is used in the cure, mitigation, treatment or prevention of disease.”

The agency said that classification of an IVDMIA “would depend on its intended use,” and that it believes that “most IVDMIAs will be either Class II or III devices.”

As an example, it cites that an indicator of a patient’s risk of cancer would likely be classified as a Class II device, which generally requires a 510(k) clearance. However, even that same device, if the intended use is to predict whether a patient should have chemotherapy would require a PMA (pre-market approval).

A PMA would require clinical study, and in such study, the companies can make no claims for the tests. Additionally, companies may be required to secure an investigational device exemption for tests in such studies.

“FDA recommends sponsors interact with the agency early and often in the development of these diagnostic assays and utilize appropriate scientific, medical and statistical expertise to assure that thresholds of safety and effectiveness are addressed,” the agency wrote in its guidance.

The guidance also states that IVDMIAs are subject to the Quality System Regulation, but it noted that it “will work with laboratories” that make these devices and that also must comply with CLIA regulations. IVDMIAs makers also must comply with the Medical Device Reporting regulation, which would require them to report to the FDA any information regarding a device suspected of causing a death or serious injury.

One of the companies that offers such tests is Genomic Health (Redwood City, California). Its OncoType DX-21 gene panel breast cancer test, for example, was touted at the 28th annual San Antonio Breast Cancer Symposium in December 2005, when study results were released. The study evaluated the
experience of four oncologists treating 68 early-stage, estrogen-receptor-positive breast cancer patients and found that knowledge of the Oncotype DX Recurrence Score, a score between 0-100 assigned based on a quantitative measurement of the expression of 21 genes, altered the adjuvant treatment administered to 25% of patients compared to physicians’ original recommendations.

“Our findings clearly indicate that assessing a woman’s individual Recurrence Score in addition to standard measures, such as patient age, tumor size and tumor grade, is critical to making well-informed treatment decisions,” said Ruth Oratz, MD, clinical associate professor, NYU School of Medicine (New York), and lead author of the study, although she was at the Rocky Mountain Cancer Centers (Denver) when completing the study.

In a research note issued by Cantor Fitzgerald & Co. (New York), George Zavoica, PhD, said he “see[s] this as an opportunity for [Genomic Health] to shape public policy and the FDA’s regulatory oversight for IVDMIs in its favor.” “In our view, the FDA’s action takes out some of the uncertainty overhanging [Genomic Health],” Zavoica wrote. “[The company] will be able to continue to sell Oncotype DX during the public comment period.”

The FDA also has issued draft regulatory guidance for the industry on commercially distributed active ingredients of medical tests, or analyte-specific reagents. ASRs are chemicals used in tests intended for use in the diagnosis of diseases and conditions and to help guide medical decision-making. The FDA said that companies that commercially distribute ASRs must follow FDA requirements for marketing an in vitro diagnostic device.

“ASRs are the building blocks of medical tests,” said Daniel Schultz, MD, director. “This guidance is intended to clarify how FDA defines ASRs and what the role and responsibilities of ASR manufacturers are so that the tests that are developed using these ingredients are as safe and effective as possible.”

The agency in 1997 issued a rule on ASRs in order to define and classify the substances, imposed restrictions on their sale, distribution and use, and established their labeling requirements.

“The ASR rule was designed to accomplish several policy objectives,” the agency said in the most recent Q&A guidance. “These include ensuring the quality of materials used as components of in-house laboratory tests, and providing appropriate labeling so that healthcare users would understand how these tests were being validated.”

In its introduction to the current draft guidance, the FDA said it is providing it “to eliminate confusion regarding particular marketing practices among ASR manufacturers.”

The agency specifically mentions two practices as being “inconsistent” with certain established rules, for example, combining or promoting the use of a single ASR with another product such as another ASR, general purpose reagents, controls, laboratory equipment, software, etc.

FDA also specifies as inconsistent the promotion of an ASR “with specific analytical or clinical performance claims, instructions for use in a particular test, or instructions for validation of a specific test using the ASR.”

“Some manufacturers have believed that when they combine a Class I ASR, which is exempt from pre-market notification requirements . . . with other products, or with instructions for use in a specific test, the product remains exempt because of the presence of an ASR,” the draft guidance stated. However, the FDA views this type of arrangement as a “test system.”

While the current ASR rule classifies most ASRs as Class I devices, in the new guidance, FDA suggests that while that is still the case, “there are some ASRs that are Class II and Class III and that must be
cleared or approved by FDA before they can be marketed in the U.S."

To meet the FDA’s definition of an ASR, it should have the following characteristics: a single moiety; a single endpoint; no instructions or performance claims and; not promoted for use on specific instruments or in specific tests or test systems.

Microarrays, which are increasingly being developed to detect disease, for example, would not fall into this category. Any example where antibodies, probes or primers are "bundled together in a pre-configured or optimized manner so that they are intended to identify and quantify more than one chemical substance or ligand," also would not be considered an ASR and would fall under FDA purview.

Also falling in the “inconsistent” with FDA thinking on ASRs category would be software for interpretation of assay results.

Regarding marketing, the FDA draft guidance suggests that manufacturers who want to market ASRs as something other than as test systems, avoid listing ASRs, general purpose reagents (GPRs) and controls in catalogues, web sites and other promotional materials.

And the agency suggests that while instructions on how to use an ASR included in packaging is acceptable, the manufacturer cannot make any claims that would indicate that “when used as directed, the ASR will perform to detect a particular chemical substance or ligand.”

The FDA suggests in its draft guidance, however, that ASRs can be used for research applications, saying the requirement for the laboratory report disclaimer applies only to clinical diagnostic use of such products.
GE’s $8.13B for two Abbott diag units leads parade of huge deals

By AMANDA PEDERSEN, KAREN YOUNG, HOLLAND JOHNSON and DON LONG

Medical Device Daily Staff

The phrase “It’s no big deal” disappeared from the vocabulary of those in and watching the clinical diagnostics and imaging industries in the period from mid-2006 to spring 2007. That’s because big deals – billions of dollars big and hundreds of millions of dollars big – seemingly were everywhere in those sectors.

Hyperbole? Well, try these numbers on for size:

$8.13 billion.
$5.3 billion.
$2.55 billion.
$2 billion.
$1.55 billion.

All have been attached to deals either completed or announced or completed during the period in question.

The biggest, GE Healthcare’s (Little Chalfont, UK) $8.13 billion plan to buy Abbott’s (Abbott Park, Illinois) in vitro and point-of-care diagnostics businesses, was unveiled in mid-January 2007 and kicked off the 2007 deal-making season in a huge way, following up on an already healthy buying spree in the previous year.

While Abbott’s Molecular Diagnostics and Diabetes Care businesses are not part of the transaction and will remain part of Abbott, the deal is plenty big without them.

GE Healthcare said the addition of the core laboratory diagnostics businesses of Abbott will broaden its diagnostic offerings and complement its existing positions in in vivo diagnostic imaging systems, as well as its molecular imaging, information technology, and patient monitoring capabilities across the complete healthcare continuum.

The divestiture was surprising to many, since Abbott is a leader in a $24 billion market that grows 6% to 8% a year. Its in vitro diagnostics business, including the point-of-care testing business formerly known as i-STAT, generated net sales of about $2.7 billion in 2006.

Miles White, Abbott’s CEO and chairman, provided a rationale for the move in terms of his company’s recent changes. In the 1980s and 1990s the core laboratories and diagnostics market was one where the most advanced assays were run on low-cost bench-top instrumentation, White said. But over the past decade Abbott has seen fundamental changes in the nature of this market.

“Today, it’s a market driven by automated, capital-intensive, mainframe systems that are integrated with institutional IT systems,” White said. “These capital-intensive technologies require a financing, sales and service infrastructure more suitable for large capital equipment manufacturers such as GE.” (See separate story, page 66.)

Just prior to the announcement of the GE-Abbott deal, Siemens Medical Solutions (Malvern, Pennsylvania) reported the completion of a deal that was shoved off the top of the valuation heap by the
GE-Abbott accord. Siemens said in early January that it had completed its $5.3 billion acquisition of Bayer Diagnostics (Tarrytown, New York), a deal that was first disclosed the previous July. Bayer Diagnostics and Diagnostic Products Corp. (DPC; Los Angeles), which Siemens acquired in 2006, were merged into a single business unit, Siemens Medical Solutions Diagnostics, on Jan. 1. That business employs more than 8,000.

For Siemens, the acquisition of Bayer provides a strong complementary fit to its April 2006 purchase of DPC for $1.68 billion. The company said that with the additions of DPC and the Bayer Diagnostics, it now holds the No. 2 position in immunodiagnostics worldwide behind Roche Diagnostics (Basel, Switzerland).

Bayer's diabetes business, as well as the contrast agent business of Schering (Berlin), which Bayer acquired for about EUR 3.7 billion in June 2006, were not included in the Siemens transaction.

In another billion-dollar-plus transaction, Eastman Kodak (Rochester, New York) said in mid-January 2007 that it had agreed to sell its Health Group to Onex Healthcare Holdings (Toronto), a subsidiary of Onex Corp.

Kodak will sell its Health Group to Onex for up to $2.55 billion. The price includes $2.35 billion in cash at closing, plus up to $200 million in additional future payments if Onex achieves certain returns with respect to its investment. If Onex Healthcare investors realize an internal rate of return in excess of 25%, Kodak will receive payment equal to 25% of the excess return, up to $200 million.

The Health Group, which had revenues of $2.54 billion for the 12 months ended Sept. 30, 2006, develops information technology; molecular imaging systems; medical and dental imaging, including digital X-ray capture; medical printers; and X-ray film.

Kodak said the deal includes the area of the business that sells X-ray film and digital X-ray machines into the non-destructive testing market, the molecular imaging systems business and the dental business.

Onex said it decided to acquire Kodak's Health Group because the business has a “great track record in delivering innovative solutions for customers around the world.”

“Kodak's Health Group has an exceptionally strong management team and we share this team’s vision for the future. We recognize that growth is critical and that digital technology is the future, and we believe strongly that customers and employees must continue to be a top priority,” said Robert Le Blanc, an Onex managing director.

In May 2006, on the heels of its sixth consecutive quarterly loss, Kodak said it was exploring strategic alternatives for the Health Group, including the possible sell-off of the business.

Robert Salmon, a spokesman for Kodak, told Medical Device Daily that at the time of the May announcement the company had decided that “in order to be truly successful and realize growth and really take the business to a whole [new level] would require an investment of resources it didn’t have.” Thus the decision to sell the Health Group to Onex, which Salmon said has a track record of being able to develop and grow its acquisitions. “We joined forces with an organization that has the resources to grow the business,” he said. He said that with deal close the Health Group will operate as a stand-alone company.

The companies said the sale would close in the first half of 2007, but that had not yet occurred when this book went to press. Kodak said it planned to use the proceeds from the sale to fully repay its roughly $1.15 billion of secured term debt.

Included in the sale are manufacturing operations focused on the production of health imaging
products, as well as an office building in Rochester. About 8,100 employees of the Health Group will continue with the business following the closing.

Kodak said that Kevin Hobert, president of Kodak’s Health Group, would become CEO of the new Health Group entity. “We have done extensive transition planning to ensure that, beginning on day one we will have the resources and a comprehensive plan to maintain our high level of service to customers,” Hobert said. “We have great products and a great team to support those products.”

Onex is one of Canada’s largest companies, with annual revenues of about C$20 billion and consolidated assets of roughly C$20 billion. It has global operations in healthcare, service, manufacturing and technology industries. The healthcare operations include emergency care facilities and diagnostic imaging clinics.

In another big-bucks deal, Quest Diagnostics (Lyndhurst, New Jersey) said in mid-April 2007 that it had agreed to buy AmeriPath (Palm Beach Gardens, Florida) for about $2 billion, including roughly $770 million in debt at closing.

AmeriPath, a company controlled by private equity investment firm Welsh, Carson, Anderson and Stowe, provides dermatopathology, anatomic pathology and esoteric testing, and has annual revenues of more than $800 million.

Quest CFO Bob Hagemann told investors during a conference call that cost synergies were not the key drivers behind the company’s acquisition of AmeriPath. Hagemann said there would be very little integration, that AmeriPath would continue to operate in much the same way as it currently does, and that Quest does not plan to close any of AmeriPath’s major facilities.

“We’re doing this because it’s a growth opportunity . . . With that said, though, there are some synergy opportunities: overhead costs, purchase logistics, and potentially some bad debt. We’ll realize some of that in the first year, with the rest of that realized in the second year,” he said.

Surya Mohapatra, PhD, CEO and chairman of Quest, emphasized the value of the $2 billion cash deal. “This acquisition will establish our leading position in cancer diagnostics with a focus on dermatopathology, anatomic pathology and molecular diagnostics,” Mohapatra said. “AmeriPath is respected for its leadership in dermatopathology and anatomic pathology, two of the fastest growing segments in diagnostic testing. Additionally, its Specialty Laboratories unit will further strengthen our hospital and esoteric testing business. The acquisition will accelerate Quest Diagnostics’ revenue and earnings growth and provide compelling benefits for patients, physicians, hospitals and payers through enhanced customer service and expanded test offerings.”

AmeriPath operates three divisions. Dermpath Diagnostics has a team of more than 80 board-certified dermatopathologists who interpret 2.4 million biopsies a year. Its anatomic pathology division, which operates under the AmeriPath brand, has expertise in gastroenterology, urology, oncology and women’s health. Specialty Laboratories, its esoteric testing business, is a full-service clinical laboratory serving hospitals, reference laboratories and physicians nationwide.

The company has about 400 pathologists and clinical scientists and nearly 4,000 employees in all.

“AmeriPath and Quest Diagnostics share a deep commitment to providing the highest quality diagnostic services to physicians and their patients,” said Donald Steen, CEO and chairman of AmeriPath. “The joining together of our companies will facilitate and accelerate our mission of becoming the leader in the innovative delivery of quality pathology disease management services.”

The transaction was expected to close during 2Q07. Quest said it would pay for the transaction, refi-
Deals

AmeriPath’s existing debt and the debt from the acquisition of HemoCue (Ängelholm, Sweden), completed earlier in 2007, with the proceeds of a new $1 billion, one-year bridge loan and a new five-year $1.5 billion term loan, both committed to be underwritten by Morgan Stanley.

Quest reported in early February that it had acquired HemoCue, a company specializing in point-of-care testing, from the private equity firm EQT II for about $420 million in cash.

Quest said the acquisition would allow it to enter the near-patient testing market and leverage HemoCue’s international presence to reach new markets worldwide. The company said it planned to link HemoCue’s handheld systems with its Care360 portal, which gives doctors access to lab and medication records, patient medical history and remote ordering of lab testing or prescriptions. HemoCue has annual revenues of about $90 million, and is a leading international provider in near-patient testing for hemoglobin. It claims a growing share in professional glucose and microalbumin testing. The company’s handheld systems are used in physicians’ offices, blood banks, hospitals, diabetes clinics and public health clinics. In developing countries these systems are used as the primary means to screen for anemia. The measurement of hemoglobin is important for patients being treated by transfusion, or undergoing dialysis or chemotherapy, where instant test results can lead to immediate treatment decisions.

Quest said that HemoCue has a strong product pipeline, based on the use of its patented microfluidic systems, and that it is currently developing new tests, including a near-patient test to determine white blood cell counts. It is designed to help determine the presence of an infection and the need for antibiotic treatment, potentially reducing the overuse of antibiotics. Quest said that the acquisition also complements its efforts in near-patient testing for infectious disease and cancer, including new tests for colorectal cancer screening and herpes simplex virus type 2.

“Technology is enabling diagnostic testing to move closer to the patient, and the acquisition of HemoCue and its exciting product pipeline gives us a strong presence in this emerging market,” said Mohapatra. “Linking near-patient testing devices to our proprietary Care360 patient-centric physician portal can provide longitudinal test reporting on a patient regardless of how or where a test was performed. This will help doctors improve the way they diagnose, monitor and treat disease.”

In yet another deal valued at more than $1 billion, Beckman Coulter (BC; Fullerton, California) was trying to complete a deal for diagnostic test manufacturer Biosite (San Diego) as this publication went to press in early May 2007. Beckman Coulter, a developer of products that automate complex biomedical tests, and Biosite, which is commercializing proteomics discoveries for diagnostics, reported entering into a merger agreement in late-March 2007 under which Beckman Coulter would acquire Biosite’s outstanding common stock for $85 a share in cash, about $1.55 billion on a fully diluted share basis. But Beckman found itself pitted against a rival bidder, Inverness Medical Innovations (Waltham, Massachusetts), which came forward with a $90-a-share offer that BC subsequently matched in early May. The outcome was unresolved at presstime. (See separate story, page 68.)

**MDS offers $615M for Molecular Devices**

MDS (Toronto) and Molecular Devices (Sunnyvale, California) reported signing a definitive agreement in late-January 2007 for MDS to acquire Molecular Devices, a provider of measurement tools for high-content screening, cellular analysis and biochemical testing, in a $615 million cash transaction. MDS expects to acquire all of the common shares of Molecular Devices for $35.50 a share. The merger agreement has been unanimously approved by the boards of both companies. MDS will begin a cash tender
offer for all of the outstanding shares of Molecular Devices. The total purchase price is made up of $585 million to purchase outstanding shares plus $30 million to purchase outstanding stock options. Excluding normal one-time merger-related expenses, the transaction is expected to be modestly accretive in 2007. It is expected to be significantly accretive in 2008 and beyond.

The acquisition marks a significant expansion for MDS, the company said. It plans to create a new business unit that will combine the Molecular Devices and MDS Sciex businesses. It will be led by the current president of MDS Sciex, Andy Boorn, PhD, who will oversee its integration and management. The combined organization will have more than 1,100 employees, including more than 250 scientists and engineers.

In a conference call, MDS President/CEO Stephen DeFalco said, “What an exciting day for MDS. I’m thrilled to be speaking to you about this deal. We have discussed many times our strategy of making acquisitions to support our three core life sciences businesses – and this one is right in our sweet spot.” He added, “This acquisition transforms Sciex from what is today – a category killer in mass spectrometry — to a much broader platform for growth.”

During the first year, DeFalco said the combined companies expect to add $190 million in revenues. For the cash transaction, the money is expected to come from the MDS balance sheet, access to its revolving credit line and the “impending proceeds from the Diagnostics [division] sale,” DeFalco said on the call.

MDS reported in October 2006 signing an agreement to sell its Canadian laboratory services business, MDS Diagnostic Services, to Borealis Infrastructure Management (Toronto) in a C$1.325 billion (US $1.2 billion) transaction. MDS said at the time that the move was designed to shift the company’s focus to the life sciences market.

“One of the most exciting parts of this deal is access to the high-content screening market,” DeFalco said. “Screening is a $2.9 billion market, and the fastest-growing part of it is high-content, which is about a $300 million market, where Molecular Devices is tied for a first-place position.”

Also, he said, in addition to a very strong intellectual property portfolio, high single-digit organic growth and a track record of product innovation, Molecular Diagnostics brings “access to a direct sales and support team of over 230 people who are positioned in the most attractive life sciences markets around the world.”

By acquiring Molecular Devices, with its “strong brand recognition and leading-edge products and capabilities,” MDS said it will strengthen its leadership position as one of the top global providers of life sciences solutions. It will now offer systems that provide high-content screening, cellular and biochemical testing for leading drug discovery and life sciences laboratories in pharmaceutical, biotechnology, academic and government institutions. Molecular Devices has an installed base of 100,000 instruments and markets its products globally through its sales and marketing offices in the U.S., UK, Germany, South Korea, China, Japan, Australia and Brazil.

MDS said it expects to realize cost synergies in the range of C$10 million to C$12 million (US$7 million) in fiscal 2007, primarily through the elimination of Molecular Devices’ public company costs, related corporate infrastructure and the opportunity to leverage “significant capabilities” across the combined global organization. In the four quarters ending Sept. 30, 2006, Molecular Devices reported revenues of $185 million and EBITDA of $38 million. The transaction was subject to regulatory and other customary closing conditions and was expected to close in 2Q07.
**Danaher wins 3-way battle for Vision Systems**

Another contested acquisition saw a move worthy of a high-stakes poker tournament, with the last player to be seated at the table apparently becoming the winner in the competition to acquire **Vision Systems** (Melbourne, Australia). **Danaher** (Washington) went all-in with its late-in-the-game, $520 million (A$3.75 a share) bid, and it appeared that neither of the other players had the stomach to call its bluff.

In early October 2006, Danaher bid topped the three-way battle for Vision, outbidding **Cytyc** (Marlborough, Massachusetts) and **Ventana Medical Systems** (Tucson, Arizona), both of which indicated that the new offer was too rich for them to match. Cytyc said that it would not raise its A$3.25 per share bid ($517 million total), and Ventana said it no longer planned to pursue the acquisition of Vision after Danaher upped the ante.

Vision Systems is a maker of instruments and reagents used in biopsy-based detection of cancer and infectious diseases. Vision’s BioSystems arm sells automated machines to pathology labs and hospitals. The company locks in customers to high-margin three- to five-year packages for the reagents used with the machines.

“Vision’s shareholders clearly benefit from this transaction, and we also recognize that Danaher and Leica Microsystems provide a unique set of opportunities for our businesses to thrive and continue to grow,” said James Fox, managing director of Vision Systems. “We are excited by this combination and look forward to capitalizing on the opportunity to better serve our customers and provide stimulating challenges for our professionals worldwide.”

Danaher’s bid, approved by Vision Systems in the absence of a higher offer, is conditional on gaining 50.1% acceptance and was expected to close in 4Q06. Both Cytyc and Ventana each own more than 10% of Vision Systems shares, enough to block Danaher from taking full ownership.

It appeared that Danaher sandbagged Ventana, terminating previously disclosed discussions regarding a potential cooperative effort to purchase Vision that had been unveiled in response to Cytyc’s increased offer for Vision.

Ventana said it would “immediately” begin to file patent litigation against Vision Systems in U.S. federal court. The company said it intended to file suit against Vision to protect its intellectual property. Ventana had deferred filing the suit pending the outcome of the bidding for Vision.

Danaher said that Vision complements its **Leica Microsystems** pathology diagnostics business that supplies laboratories with equipment such as high-end microscopes. It said the combination with Vision would create “a leading global supplier of innovative solutions serving the anatomical pathology market. Together Vision and Leica Microsystems would offer a complete line of specimen preparation and diagnostic instruments while offering the advanced chemistries critical to the future of pathology.”

“Vision has an attractive pathology diagnostics instrument and consumable product offering that fits very well with the growth strategy we are pursuing for our Medical Technology Platform,” said H. Lawrence Culp Jr., president/CEO of Danaher. “Specifically, we believe that Vision’s strength in rapid tissue processing and workflow-optimized advanced staining systems will allow us to drive growth by offering . . . improved productivity and advanced diagnostic technologies for use in clinical pathology laboratories.” Danaher said its offer price, on a per-share basis, was about 15% higher than Cytyc’s already increased, unconditional bid of A$3.25.

Not entirely folding its cards, Cytyc said that its bid remained open, calling it “the only offer current-
ly open for shareholders to accept and is not subject to any conditions, unlike the offer by Danaher, which Cytyc understands will not be available for shareholders to accept until early November.” ■
MDS, Roche, Illumina among big wheelers and dealers in sector

By HOLLAND JOHNSON, KAREN YOUNG, DON LONG and AMANDA PEDERSEN

A number of diagnostics and imaging sector merger-and-acquisition deals that carried significant valuations in their own right were overshadowed by the billion-dollar-plus transactions that dominated the deal-making headlines in the mid-2006 to May 2007 timeframe.

For example, MDS (Mississauga, Ontario), a provider of products and services to the global life sciences markets, reported completing its $615 million all-cash acquisition of Molecular Devices (Sunnyvale, California) in late-March 2007.

The merger, first disclosed in late January, followed completion of a tender offer by MDS for all of the shares of Molecular Devices for $35.50 a share. At the time the merger became effective, MDS owned in excess of 90% of Molecular Devices’ issued and outstanding shares. As a result of the merger, any Molecular Devices shares not tendered in the tender offer have been converted into the right to receive $35.50 per share.

Following the expiration of the initial offering period, MDS launched a new business unit called MDS Analytical Technologies, combining the Molecular Devices and MDS Sciex businesses to serve pharmaceutical, biotechnology, government, and academic laboratory customers with solutions to improve the speed and efficacy of their drug discovery and development efforts.

Andy Boorn, PhD, president of MDS Sciex, will lead the new unit and will launch integration plans to bring together the two businesses.

In late February, MDS reported concluding the sale of its Canadian laboratory services business, MDS Diagnostic Services, to Borealis Infrastructure Management (Toronto) in a deal valued at C$1.325 billion. The deal was first unveiled late in 2006.

From the C$1325 billion, MDS said it would realize net proceeds of about C$1.052 billion, made up of $977 million in cash and $75 million in an unconditional note, payable in March 2009.

The laboratory services business will continue to operate under the name MDS Diagnostics Services until later in 2007.

“With this transaction, we have closed a chapter in our company’s history by completing our transition to a global life sciences company,” said Stephen DeFalco, president/CEO of MDS. “With our plans to acquire Molecular Devices Corp., we have begun a new and exciting chapter focused on growth.”

Roche (Basel Switzerland) reported in early April 2007 that it had agreed to acquire BioVeris (Gaithersburg, Maryland) for $21.50 per share in cash, or a total of about $600 million. The price represented a 58% premium to the closing price of $13.60 for BioVeris stock the day prior to the announcement of the deal.

Roche, the No. 1 clinical diagnostics company in the world, said the purchase would allow it to expand its immunochemistry business from human diagnostics into new segments such as life science research, patient self-testing, veterinary testing, drug discovery, drug development and clinical trials. By acquiring BioVeris, Roche will own the complete patent estate of the electrochemiluminescence (ECL)