

**MEDICAL DEVICE DAILY™**

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ADVANCES

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IN CANCER

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DIAGNOSIS

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AND

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TREATMENT

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# Diagnostics and device-based treatments key to cancer fight

As Contributing Writer Michael Simonsen, PhD, noted in his report from last year's annual meeting of the **American Society of Clinical Oncology** (ASCO, Alexandria, Virginia) in Chicago, the continued increase in cancer incidence is resulting in rapid growth in the number of individuals alive with cancer, leading in turn to greater demand for products and services for cancer diagnosis, treatment and on-going monitoring.

After heart disease, cancer is the second-leading cause of death. And for people under age 85, cancer is the leading cause of death in the U.S. While significant progress has been made in improving cancer survival rates — as evidenced by a drop in cancer deaths in the U.S., in both 2003 and 2004 — the number of new cases of this disease continues to climb.

The ASCO meeting provided what Simonsen characterized as “a window on recent developments in cancer diagnostics and treatment.” It highlighted in particular the expanding role of molecular diagnostics and molecular imaging in the management of a wide range of cancers.

Genetic tests, coupled with proteomic markers, are increasingly being employed for therapy guidance, including both initial selection of therapy as well as monitoring of response. Molecular profiling of patients is being employed both to assess cancer risk and also to determine optimal drug treatment, and newer targeted drugs require the use of molecular testing to identify patients who will have a positive response to therapy.

Cancer screening is another important area, with advances seen in imaging for early detection of cancer as well as genomic testing to identify high-risk individuals.

Advances in cancer prevention were described at the conference that could reduce the number of new patients in the future but create a new market for prevention products, while advances in informatics are seen as a means of more efficiently managing the complexities of the cancer diagnostic and therapeutic process.

The improvement in cancer survival is the result of both earlier detection of cancer using advanced screening and diagnostic methods, as well as improved therapies, particularly molecularly targeted treatments that provide effective ablation of cancer cells with minimal effects on normal tissue. Molecular diagnostics play a role in both applications, providing a new approach to identify those at increased risk for cancer so they can be more closely monitored, as well as providing a tool for guidance of targeted therapies that have been shown to result in significant improvements in survival of a number of cancers.

Another contributing writer, Larry Haimovitch, covered the annual meeting of the **American Society for Therapeutic Radiology and Oncology** (ASTRO; Fairfax, Virginia) in Los Angeles in October 2007, noting in his report that progress in improving cancer therapy is advancing on many fronts. For example, in breast cancer less-invasive breast conserving surgery (lumpectomy) and post-op accelerated partial breast irradiation (APBI) have made a significant impact. APBI has been challenging whole-breast, external-beam radiation in the past several years for post-lumpectomy patients. Consistent with the growth of less-invasive surgery in other surgical specialties, this trend is accelerating.

A third report worth citing is Staff Writer Lynn Yoffee's story on new **American Cancer Society** (ACS; Atlanta) guidelines for colorectal cancer screening which now include computed tomography colonoscopy (CTC), a 15-minute test that does not require sedation, invasive scopes or recovery time. As she noted, the addition of this test to the ACS guidelines is an effort to encourage more people to do colon cancer screening to avoid what has become the second-leading cause of cancer death in the U.S.

Both CTC and stool DNA testing were added to the ACS' screening guidelines, which were developed in collaboration with the U.S. Multi Society Task Force on Colorectal Cancer and the **American College of Radiology** (Reston, Virginia).

"There is finally, over the last four to five years, enough accumulated evidence supporting the ability of CTC to detect both colon polyps and cancers at a high rate," Durado Brooks, MD, ACS' director, Prostate and Colorectal Cancer, Cancer Control Science Department, told Yoffee while being interviewed for the story.

According to the ACS, half of all Americans who should be getting screened for colon cancer are not. Although traditional colonoscopy is the preferred screening strategy for colorectal cancer, CTC and stool tests may encourage hesitant patients to be screened. However, if one of those tests reveals a suspicious site, a colonoscopy would still have to be performed. Until insurers and Medicare implement reimbursement strategies in line with the new guidelines, adoption of the test may be slow.

"Medicare reimbursement for traditional colonoscopy is significantly lower than what is charged by most colonoscopy facilities," Brooks said. "If you talk with patients, particularly those outside of the Medicare system, the charges vary wildly so it's difficult to put an average cost on colonoscopy. With CTC, it's further complicated because up to this point almost no insurers pay for it as a screening tool."

A study in the fall of 2007 comparing CTC with traditional optical colonoscopy found that the tests yielded similar results.

This sourcebook focuses on the key areas of interest and importance for technology developers and companies as they look to the future. *Advances in Cancer Diagnosis and Treatment* represents the first such collection of information – just under 200 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 covering the med-tech industry.

On the pages that follow, you'll find overviews of those areas we have judged to be of the most interest moving forward. In the Overview section, we take a look at Where We Are as a sort of scene-setter for what's happening in the oncology diagnostics and device-centered therapy sector. Then in What's Ahead, we do a little crystal ball-type thinking about where the industry is headed. In Legislative/Regulatory, we report on some of the efforts on both the legislative and regulatory sides of government that affect the sector. Finally, the Deals chapter covers some of the most significant mergers & acquisitions activity between July 2007 and roughly March 1 of 2008. 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 – 90-some pages devoted to eight chapters ranging from Breast Cancer to Surgery/Radiotherapy. In each of these chapters, we take a 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.

The third section, Miscellaneous, includes chapters on Emerging Companies, International, Products and Research. All are designed to give you an idea of the activity taking place under each of those designations.

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 many hundreds – perhaps even thousands – involved in this sector overall. What we have attempted to do is to make note of activities involving 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 our two monthlies, *Biomedical Business & Technology* and *Cardiovascular Devices & Drugs*. I especially want to cite the work of Executive Editor Don Long, Managing Editor Holland Johnson, Senior Production Editor Rob Kimball, Staff Writers Amanda Pedersen, Omar Ford, Lynn Yoffee and Karen Young, and Washington Editor Mark McCarty in producing the materials included in this book.

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

— *Jim Stommen, National Editor*

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