Strong North American SPECT/CT Market

Frost & Sullivan (Palo Alto, CA), a market growth consulting and research firm, released analysis on February 25 indicating that the North American nuclear medicine equipment market may recover more quickly than expected from the effects of the Deficit Reduction Act (DRA) of 2005. Driving this positive news are the SPECT and SPECT/CT segments of the market, which, according to the analysis, are opening up "numerous lucrative opportunities in niche markets such as neuroendocrine tumor imaging." The North American SPECT and SPECT/CT markets earned revenues of $298.4 million in 2007 and are estimated to reach $325.3 million in 2014.

In a related press release, Frost & Sullivan Research Analyst Travis Chong said: "With the adoption rate of SPECT/CT progressively increasing, opening up new market potential for both imaging system vendors and radiopharmaceutical agent companies, the rising numbers of new niche markets are expected to drive growth in this segment, creating opportunities for revenue expansion and establishing SPECT/CT as a mainstream tool in nuclear medicine."

The analysis noted that not all aspects of the SPECT/CT market are positive. Participants in niche markets must contend with the peculiar dynamics of new and targeted technologies, as well as prepare to deal with challenges arising from the lack of novel imaging agents. SPECT/CT could experience slow clinical adoption because of reimbursement reductions, tight end-user capital budgets, narrow physician referral bases, and low levels of physician education. "Vendors could also be significantly hindered by inadequate technologist training for specialty markets," said Chong. "However, they can improve this issue by working with consumers to offer informative training programs. This way, vendors will not only enhance physician education and technologist training levels but also manage to strengthen brand loyalty and recognition, which in turn, will translate into increased revenue potential." Once they convey the importance of SPECT and SPECT/CT equipment to end users, he added, vendors will look to phase out traditional product models with scalable system platforms. A bigger market for scalable platforms is expected because of their increased clinical versatility, enabling end users to adapt systems to meet specific needs as workflow demands and imaging operations evolve.

"Companies should also look to increase both organic and external research and development investments in solid-state technology and scintillation detection," said Chong. "Solid-state technology has proven to have high reliability, low manufacturing costs, less noise, and high sensitivity, as well as excellent spatial and energy resolution." In the future, the integration of solid-state technology is expected to advance hybrid technology and drive product innovation, creating novel systems such as SPECT/MR units.

For more information on the North American Nuclear Medicine Equipment Market analysis by Frost & Sullivan, see: medicalimaging.frost.com.

Frost & Sullivan

IOM Recommends National Health Product Review

A report released on January 24 by the Institute of Medicine (IOM), part of the National Academies, offered a blueprint for a national program that would assess the effectiveness of clinical services and provide unbiased information about which health care products are effective. *Knowing What Works in Health Care: A Roadmap for the Nation* recommended that Congress direct the U.S. Department of Health and Human Services to establish a program with the authority, expertise, and resources necessary to set priorities for evaluating clinical services and to conduct systematic reviews of the evidence. This program would also be responsible for developing and promoting rigorous standards for clinical practice guidelines, which could "help minimize the use of questionable services and target services to the patients most likely to benefit."

"We need a way to synthesize data about the effectiveness of health care products and services in a standardized, objective fashion that will be considered reliable and trustworthy by all decision makers," said Barbara J. McNeil, MD, PhD, from Brigham and Women's Hospital (Boston, MA), who chaired the committee that prepared the report. She added, "A system coordinated by a single, national entity that can prioritize and coordinate these evaluations would enable us to sort the wheat from the chaff and make sense of it all."

The report noted that although several organizations conduct evidence reviews and develop clinical practice guidelines, a single entity with the authority and resources is needed to determine what works. The authors cited a lack of coordination leading to duplication of effort, numerous competing practice guidelines, and uncertainty about which study results and guidelines are the most reliable and objective. "This situation complicates the push to empower individuals to become more engaged in choosing and managing their care," stated a press release issued to accompany the report.

The committee noted that the proposed national program, if established in a way that ensures transparency, scientific rigor, and high standards for accountability and objectivity, would be a trusted resource for reliable information on the effectiveness of health services. One current challenge is the sheer volume of information available. Thousands of new clinical studies are

published each year, producing amounts of medical data that many providers, patients, health plans, and others find unmanageable. Research has also shown that the significant proportion of evidence reviews financed by manufacturers or vendors is more likely to show effectiveness, which leads some to question whether the cumulative body of evidence for any given health care product or service may be biased.

The committee did not make cost-related recommendations. The report noted, however, that reliable cost effectiveness analysis depends on high-quality evidence on the effectiveness of products and services. Copies of the report are available at: www.nap.edu.

Institute of Medicine

Better Medical Device Info Needed

Researchers from the University of California–San Francisco (UCSF) and other institutions provided perspectives and analyses in the January issue of the *Journal of General Internal Medicine* (2008;23[suppl1]:1,57–63) on the current approval process for medical devices, noting that the process lacks the rigorous review used for pharmaceuticals. The special supplement to the journal, which was devoted entirely to medical devices, was edited by UCSF researchers Mitchell D. Feldman, MD, MPhil, and Jeffrey A. Tice, MD.

Feldman and Tice placed special emphasis on the difficulty that both patients and practitioners encounter in finding sufficient information with which to make decisions about new devices. "These days, patients are asking their doctors for the newest technologies from genetic tests to specific radiation treatments, and many physicians don't know where to turn for the latest evidence-based information," said Feldman in a UCSF press release on the study. "Sometimes, the only information out there is what the manufacturer provides."

The UCSF analysis evaluated the federal review process, the method by which devices come to market, how the scientific literature reports on clinical trials involving medical devices, and the effectiveness of independent review boards in improving a technology's medical benefit to patients. Out of the thousands of medical technology applications submitted annually to the U.S. Food and Drug Administration (FDA), fewer than 100 undergo the kind of scrutiny required for new drugs, according to information cited in the report. Most new applications are approved through an expedited FDA process that considers new devices similar to those already approved. The agency also relies on manufacturers and clinical investigators to initiate recalls and failure reports when a technology is not beneficial or is potentially harmful to patients.

"FDA approval should be the start of the process toward clinical application, not the end," Feldman said. "Physicians and patients just aren't aware of the limitations of the FDA process of initial assessment and oversight of new medical technologies. Assessments by objective entities are a necessary addition to FDA approval—so that deficiencies in clinical evidence and patient safety issues that may arise after approval are recognized before widespread adoption into clinical practice."

Feldman and Tice cited their experience with increased consultation with independent review organizations as 1 remedy. They described the activities of the California Technology Assessment Forum (CTAF), which has public meetings and a review board of experts in medicine, representatives from medical professional societies, technology manufacturers, policy makers, and insurance providers. CTAF selects devices for review based on their impact and the availability of relevant clinical data. "In order to be considered in an assessment, CTAF requires that information already be published or accepted by a peer-reviewed journal. This encourages companies to make their trial results available to the public," said Tice. "CTAF also requires improvements in patient-oriented outcomes, not surrogate markers. For example, we want to see improvements in disease-free survival and patient quality of life, not just a reduction in tumor size." Once findings are presented, the technology's manufacturer has the opportunity to give testimony, and eventually the board makes recommendations based on the body of information presented. The authors recommended similar measures to increases health care professionals' awareness of "the potential promise and pitfalls of new technology."

University of California–San Francisco

AAPM Report on CT Radiation Dose

The American Association of Physicists in Medicine (AAPM) released in January a report on CT radiation dose management, providing information on the latest dose reduction technology and recommending standardized ways of reporting doses. The report, *Measurement, Reporting, and Management of Radiation Dose in CT. Report of AAPM Task Group 23 of the Diagnostic Imaging Council CT Committee,* is targeted at radiologists, medical physicists, and other medical professionals and outlines the best ways to measure, manage, and prescribe radiation dosages. It also gives an overview of ways that physicians can optimize imaging with CT scanners to reduce to a minimum the amount of radiation to which patients are exposed, while still acquiring high-quality images.

"The medical applications of CT have grown tremendously in the last decade as the technology has become more and more sophisticated," said Cynthia McCollough, PhD, chair of the AAPM task group that prepared the report. "In the era of increasingly personalized medicine, the report provides a roadmap for doctors and medical physicists to tailor the CT radiation dosages to individuals."

The information contained in this report is crucial, added McCollough, because it can help medical practitioners take full advantage of sophisticated CT technology. "Essentially, all modern CT systems can be equipped with automatic exposure control systems. . . .We believe that this report

equips users to properly describe and manage CT dose levels." The full report is available at: www.aapm.org/pubs/reports/RPT_96.pdf.

American Association of Physicists in Medicine

CMS: Steady Growth in Health Spending

The Centers for Medicare and Medicaid Services (CMS) issued a report on February 26 estimating growth in health care spending in the United States to have been at 6.7% in 2007 and projecting that average annual growth would remain near that rate throughout the next decade. The analysis was prepared by the CMS Office of the Actuary and published online in *Health Affairs*. Over the full projection period (2007–2017), annual growth in health spending is anticipated to be higher than annual growth in both the overall economy (4.9%) and general inflation (2.4%). As a percentage of gross domestic product (GDP), health care spending in 2007 was estimated to be 16.3%, up slightly from 16.0% in 2006. By the end of the projection period, annual health care spending in the United States is expected to reach more than $4.3 trillion and account for 19.5% of GDP.

Health spending growth through public programs, however, is expected to slow to 6.8% in 2008, after the 8.2% growth in 2006 that resulted, in part, from the rollout of Medicare Part D drug benefits. Public health spending growth is expected to gradually increase toward the end of the projection period, as more of the baby boom generation enrolls in Medicare.

Growth in private health expenditures (which include out-of-pocket and private health insurance spending) is estimated to have rebounded to 6.3% in 2007 after the somewhat slow growth of 5.4% in 2006 that was related to the implementation of Medicare Part D. Private spending growth is expected to peak in 2009 at 6.6%, then decelerate through 2017 in response to projected slower economic growth.

Prescription drug spending growth is estimated to have slowed to 6.7% in 2007 (from 8.5% in 2006), driven largely by slower rises in drug prices. For 2008 through 2017, prescription drug spending is projected to accelerate, in part as a result of leveling off of growth in generic sales. The Medicare Part D benefit, however, is expected to have "very little impact" on total national health expenditure growth through 2017, because per capita spending growth for Medicare beneficiaries is expected to be identical to that of the rest of the population.

Hospital spending growth is estimated to have accelerated from 7.0% in 2006 to 7.5% in 2007, partly because of higher Medicaid payment rates. Hospital spending growth is then projected to decrease slightly though the rest of the projection period as growth in demand for hospital services is expected to slow.

Medicare spending growth is estimated to have slowed to 6.5% in 2007, after the 18.7% growth in 2006. In the latter years of the projection, Medicare growth is expected to accelerate, reaching 8.0% by 2017, as the baby boom generation begins to enroll in the program. After a decline of 0.9% growth in 2006, Medicaid spending growth is estimated at 8.9% for 2007. On average, Medicaid spending is expected to grow 7.9%/y over the projection period and account for 16.8% of total health care spending by 2017.

These and other health care spending projection data can be found on the CMS Web site at: www.cms.hhs.gov/NationalHealthExpendData/03_NationalHealthAccountsProjected.asp.

The Centers for Medicare and Medicaid Services

FDA Draft Guidance on Industry Medical Publications

The U.S. Food and Drug Administration (FDA) on February 15 issued draft guidance on "Good Reprint Practices" for industry use in the distribution of medical or scientific journal articles and reference publications that involve unapproved uses of FDA-approved drugs and medical devices. "Articles that discuss unapproved uses of FDA-approved drugs and devices can contribute to the practice of medicine and may even constitute a medically recognized standard of care," said Randall Lutter, FDA deputy commissioner for policy. "This guidance also safeguards against off-label promotion."

Section 401 of the FDA Modernization Act previously set out guidelines that allowed the dissemination of information on unapproved uses of FDA-approved products. If the guidelines were met by manufacturers, the dissemination of such materials was not viewed by the FDA as evidence of an intent to promote the product for an off-label use. However, Section 401 expired on September 30, 2006.

The FDA's "Good Reprint Practices" draft guidance recommends principles that manufacturers should follow when distributing scientific or medical journal reprints, articles, or reference publications. One of the principles is ensuring that the article or reference is published by an organization with an editorial board. The organization also should fully disclose any conflicts of interest or biases for all authors, contributors, or editors associated with the journal article. Articles should be peer reviewed and published in accordance with specific procedures.

In addition, the draft guidance recommends against distribution of special supplements or publications that have been funded by 1 or more of the manufacturers of the product or products in the publications. Articles that are not supported by credible medical evidence are considered false and misleading and should not be distributed. The FDA retains legal authority to determine whether distribution of an article or publication constitutes promotion of an unapproved "new use" or whether such activities cause a product to be considered misbranded or adulterated under the Federal Food, Drug, and Cosmetic Act.

The FDA will accept public comments on the draft guidance, available at www.fda.gov/oc/op/goodreprint.html, through April 15. To submit comments via the Internet, go to

Docket Number FDA-2008-D-0053 on the Regulations.gov Web site.

U.S. Food and Drug Administration

Health Plans Target Imaging

The Center for Studying Health System Change (HSC; Washington, DC) released on February 21 the results of a study suggesting that health plans are increasing efforts to slow the proliferation of advanced imaging services, including CT, PET, MR, and nuclear cardiology studies. "Health plans are targeting selected, high-cost services, such as advanced imaging, for more aggressive oversight rather than imposing stricter controls across all services, hoping a targeted approach will help avoid physician and patient backlash against perceived intrusion on physician autonomy," said Paul B. Ginsburg, PhD, president of HSC, a nonpartisan policy research organization funded in part by the Robert Wood Johnson Foundation.

According to the report, health plans do not want to revive the physician backlash against managed care seen in the 1990s and so are instituting requirements perceived to be less intrusive and burdensome. Some physicians, however, described the requirements as administratively onerous and as constituting obstacles to patient care. "Despite physician objections, health plans generally have stood firm because they believe the cost savings and patient safety gains outweigh the negatives," said HSC Health Researcher Ann Tynan, MPH, coauthor of the study. Several strategies are being used, sometimes in concert:

- A few health plans have emphasized working collaboratively with physicians to decrease imaging utilization by using claims data to identify patterns of questionable imaging use by individual physicians. Plans then provide information to physicians to initiate discussions about appropriate imaging use. Some plans provide physicians with guidance on imaging appropriateness, generally in the form of evidence-based guidelines developed by professional societies.
- Some health plans require prior authorization for advanced imaging studies, meaning physicians must request and receive approval before conducting imaging studies. Lacking such approval, health plans typically deny payment to the provider performing the imaging study, despite the fact that a different provider may have ordered the study. A Cleveland, OH, health plan, for example, instituted a prior authorization program for advanced imaging studies after observing an annual 20% increase in utilization. After instituting prior authorization, the plan saw a large reduction in the growth rate of advanced imaging utilization but experienced a denial rate of only 1.5%.
- Credentialing of imaging equipment and physicians who interpret imaging studies is another strategy used by a smaller number of health plans but being contemplated by others. Credentialing requirements limit the number of service sites and physicians that a plan will reimburse for advanced imaging studies. Credentialing of imaging equipment means that qualified professionals regularly inspect the equipment to ensure that it is functioning properly and meets certain standards developed by medical professional societies and accreditation organizations. Plans also credential physicians performing and interpreting imaging studies. They require physicians to meet certain training and education standards to be included in the plan's network and receive payment for imaging services. This reflects concerns that some physicians with in-house imaging equipment are insufficiently trained to interpret test results accurately.

The study's findings are detailed in *Health Plans Target Advanced Imaging Services: Cost, Quality and Safety Concerns Prompt Renewed Oversight*, available at: www.hschange.org/CONTENT/968.

Center for Studying Health System Change

NRC Special Inspection Focuses on Generators

The U.S. Nuclear Regulatory Commission (NRC) on February 1 issued a Confirmatory Action Letter to Mallinckrodt, Inc. (also known as Covidien Imaging Solutions; Maryland Heights, MO), and announced that a special inspection team had been formed to evaluate events surrounding problems with the company's ^{99}Mo/^{99m}Tc generators. On January 11, Mallinckrodt began receiving information from customers that liquid withdrawn from the generators showed higher-than-usual levels of ^{99}Mo. The NRC learned of the increased levels on January 24 and initiated discussions with Mallinckrodt to understand the circumstances and actions the company would take to address the issue and prevent recurrence. By January 31, the company had received information that this problem had been identified in more than 100 generators. The company's commitment to investigate and remedy the problem was detailed in the February 1 Confirmatory Action Letter. The special inspection team was dispatched to evaluate the event, the company's response to the event, the company's past actions related to higher levels of ^{99}Mo in solution withdrawn from the generators, and the company's follow-up on commitments described in the Confirmatory Action Letter.

"We need to make sure we understand what caused the higher levels of ^{99}Mo in the solution withdrawn from the generators and to evaluate the company's response to the event," said Mark Satorius, deputy regional administrator for the NRC Region III Office. "We also need to gain confidence that this problem will not recur."

On Jan. 27, Mallinckrodt began including a notification in all shipments to its generator customers regarding the presence of elevated levels of ^{99}Mo.

"Based upon the preliminary results of our investigation into the cause for the presence of elevated levels of ^{99}Mo in solution drawn from some of our generators, Covidien has already taken actions it believes will help to mitigate this issue," JoAnna Schooler, spokeswoman for Covidien, told the *St. Louis Business Journal* on February 6. "Covidien is also reminding customers to follow package labeling for use of its generators, which requires the testing of each dose drawn from a generator for compliance with product specifications. Covidien is cooperating fully with the NRC."

The special inspection will continue until the inspection goals are achieved, and the special inspection team will issue its report about 30–45 d after the completion of the inspection. The report will be available from the Region III Office of Public Affairs and in the agency's online document library at: www.nrc.gov/reading-rm/adams/web-based.html.

Nuclear Regulatory Commission
St. Louis Business Journal

DOE Technology Transfer Policy

U.S. Secretary of Energy Samuel W. Bodman issued a policy statement on February 8 on Department of Energy (DOE) efforts to transfer state-of-the-art technologies from its national laboratories and facilities to the marketplace. The policy lays out guiding principles, responsibilities, and a review process designed to deploy new technologies and to ensure that continuity and uniformity of technology transfer activities are maintained throughout DOE. This policy builds on actions in June 2007 that designated Under Secretary for Science Raymond Orbach, PhD, as DOE technology transfer coordinator and chair of the Technology Transfer Policy Board. Since those actions, the coordinator and policy board have initiated a number of activities, including a review of technology transfer mechanisms that are executed across the DOE complex, in an effort to streamline and simplify transactions so that agreements can be executed more quickly.

Technology transfer is the process by which knowledge, intellectual property, and/or capabilities are transferred to any other entity, including private industry, academia, state and local governments, or other government entities, to meet public and private needs. DOE's technology transfer activities will have special emphases on "enhancing the nation's energy security, scientific discovery, economic competitiveness, and quality of life through innovations in science and technology." The most recent policy statement emphasizes the need for timely conclusion of negotiations to encourage universities, nonprofit institutions, and the private sector to partner with DOE facilities.

Ohrbach established the Technology Transfer Working Group, which includes representatives from DOE national laboratories, other DOE facilities authorized to conduct technology transfer activities, and federal field offices that oversee those activities. The group, along with the policy board, plans to release and submit to Congress a technology transfer execution plan this spring.

The complete policy statement and additional information on DOE technology transfer are available at: www.doe.gov/media/Policy_Statement_on_Technology_Transfer.pdf.

U.S. Department of Energy

NRC Announces New Strategic Plan

On February 19, the Nuclear Regulatory Commission (NRC) issued its new *Strategic Plan for Fiscal Years 2008 to 2013*, establishing the ways in which the agency intends to carry out its mission by licensing and regulating the safe and secure use and management of radioactive materials. "This Strategic Plan reflects real-world changes and describes how the NRC as a strong, independent, and stable regulator will continue to ensure the safe use of radioactive materials and nuclear power in a dynamic environment," said NRC Chair Dale Klein.

The strategic plan set forth twin goals of safety and security, with much of the emphasis on regulatory processes and nuclear power reactors. The NRC also emphasized the importance of effective leadership and the relationship between human capital, knowledge management, and space challenges that must be addressed to ensure that the agency can succeed.

The new strategic plan (NUREG-1614, Volume 4) is available on the NRC's Web site at: www.nrc.gov, in the lower left-hand corner of the home page.

U.S. Nuclear Regulatory Commission