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President Proposes $1 Billion Increase For NIH In FY2011; Cancer A High Priority

By Kirsten Boyd Goldberg

President Barack Obama's FY2011 budget request includes $32.2 billion for NIH, an increase of $1 billion, or 3.2 percent.

Cancer and autism are listed as "high-priority areas" for the administration. NCI would receive $5.26 billion, an increase of $162.9 million—the largest dollar increase proposed for any of the NIH institutes—over the current budget of $5.1 billion.

NCI plans to spend $2.2 billion on research project grants, to fund 1,220

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In the Cancer Centers:

M.D. Anderson And Chaim Sheba Medical Center To Collaborate On Training, Treatment, Research

M.D. ANDERSON CANCER CENTER and the **Chaim Sheba Medical Center** in Israel signed a Sister Institution Relationship agreement for broad-scale cooperation in oncology training, treatment and research. The agreement includes cooperation in physician education and training, clinical services, research collaborations, quality assurance programs, faculty exchange visits, scientific endeavors, nursing and other technical support staff training.

Key to the agreement is collaboration in translational research via exchange of technologies and knowledge between the institutions and establishment of joint translational research efforts to improve care for cancer patients. Researchers and clinicians will have access to the large clinical cohorts and tissue banks available at M. D. Anderson and Sheba. In addition, patients at both institutions can participate in clinical trials conducted on novel therapeutics, medical devices and diagnostic tools developed by Sheba or M. D. Anderson.

"This is the first agreement of its type for an Israeli hospital; it is a pioneering breakthrough that will significantly add to the international-class-level medicine we conduct at Sheba," said Sheba CEO and professor **Zeev Rotstein**.

Leading the collaboration at M.D. Anderson will be **Raphael Pollock**, professor and head of the division of surgery. At the Sheba Medical Center, oncologist **Amir Onn** will lead the program.

The first Sheba Medical Center doctor to benefit from a fellowship under the new agreement will be **Aviad Hoffman**, a surgical oncologist who

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NCI Plans To Fund More Cancer Centers In FY2011

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competing RPGs, a decrease of 206 from FY 2010. About 3,898 noncompeting RPGs awards, totaling $1.7 billion, would be funded.

NCI plans to provide a 2 percent inflationary increase for non-competing and competing grants.

The FY 2011 budget request for the Cancer Centers, Specialized Centers, and Specialized Programs of Research Excellence program is $569.682 million, an increase of $25.333 million, or 4.7 percent over the FY 2010 Enacted level.

NCI plans to expand the number of cancer centers, according to the institute's Congressional Justification document, available at http://officeofbudget.od.nih.gov/pdfs/FY11/NCI.pdf.

NIH estimates it will support a total of 37,001 research project grants in FY2011, including 9,052 new and competing awards. The total number of grants would be 200 more than the current year, but the budget proposes to fund 200 fewer competing awards than this year.

According to budget documents, the increase "will be guided by NIH's five areas of exceptional research opportunities: supporting genomics and other high throughput technologies; translating basic science into new and better treatments; reinvigorating the biomedical research community; using science to enable health care reform; and focusing on global health."

NIH budget documents are available at http://officeofbudget.od.nih.gov/br.html.

"From day one, President Obama has said we need to put science first," HHS Secretary Kathleen Sebelius said in a Feb. 1 press conference. "That's how our department runs. And that's reflected in our budget. Whether fighting a pandemic, protecting food safety, or transforming the health care system with electronic medical records, the investments we've made have been guided by some of the finest scientific and medical experts in the world."

Sebelius said the "additional billion-dollar investment in cutting edge science" during "this restrained budget time," demonstrated the President's commitment to medical research.

Sebelius said the budget request "makes a serious investment in the battle against smoking." Last year, Obama signed the Family Smoking Prevention and Tobacco Control Act, which gave FDA authority to regulate tobacco.

The budget includes $450 million from user fees to reduce tobacco use in minors by regulating marketing and distribution of tobacco products, promoting public understanding of harmful constituents of tobacco products, and reducing the toll of tobacco-related disease, disability, and mortality.

Also, the budget targets $954 million from CDC, NIH, and the Substance Abuse and Mental Health Services Administration to help reduce smoking and support research on preventing tobacco use, understanding the basic science of the consequences of tobacco use, and improving treatments for tobacco-related illnesses.

The budget includes $25 million for advancing regulatory science at FDA, including $15 million for nanotechnology related research. The additional resources will also enable FDA to update review standards and provide regulatory pathways for new technologies, such as biosimilars.

The FDA budget could increase by 23 percent from the current $3.3 billion to $4 billion if Congress enacts new user fees on food producers and generic drug makers. The tax-funded portion of the agency's budget would increase 6% to $2.5 billion from $2.36 billion. FDA budget documents can be accessed from www.fda.gov.

The Agency for Healthcare Research and Quality would receive an increase of $261 million, including program support costs, for new research projects.

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Evidence Reviews:

No Benefit Seen For Biomarker Testing In Oncology—AHRQ

By Paul Goldberg

The value of testing for biomarkers in oncology cannot be evaluated based on existing evidence, the Agency for Healthcare Research and Quality said in a draft report now being circulated as part of peer review.

The report summarizes a technology assessment conducted by the Tufts Evidence-based Practice Center under contract from AHRQ and is not directly connected to any coverage policies.

The technology assessment reviewed the evidence on the benefits and harms of three pharmacogenetic tests employed for three different diseases pertinent to the Medicare beneficiary population: variations in *CYP2D6* and response to tamoxifen in breast cancer; variations in *KRAS* and response to cetuximab and panitumumab in colorectal cancer and variations in *BCR-ABL1* and response to imatinib, dasatinib and nilotinib in chronic myeloid leukemia.

"In in the absence of data that can address its clinical utility and value, integration of pharmacogenetic testing in the healthcare system is not straightforward," the report states. "Before clinical implementation, evidence is necessary to ensure that the application of pharmacogenetic testing results in meaningful improvements in patient outcomes."

The reviewers asked the following questions:

1. Does the genetic test result predict response to therapy?

2. What patient- and disease-related factors affect the test results, their interpretation or their predictive response to therapy?

3. How does the gene testing impact the therapeutic choice?

4. What are the benefits and harms or adverse effects for patients when managed with gene testing?

The review focused on papers that reported patient-relevant outcomes, including mortality, disease progression and treatment failure stratified by the genetic factor.

The literature searches didn't identify any studies that could be used to answer Questions 2, 3 or 4.

The answers to Question 1 follow:

Variations in KRAS and response to cetuximab and panitumumab in colorectal cancer

We identified 31 eligible studies. Of those, 26 were conducted in the second-line metastatic setting, three were conducted in the first line metastatic setting and two were conducted in the neoadjuvant setting.

When treated with anti-EGFR antibodies, patients with *KRAS* mutations were less likely to experience treatment benefit, compared to patients whose tumors were wild-type for *KRAS* mutations, for all outcomes assessed.

These results were confirmed in several RCT-based analyses of progression-free survival that demonstrated a significant treatment-by-*KRAS* mutation interaction in three out of the four cases where such analyses were reported.

The direction of effect was consistent among studies, and formal significance was achieved in the majority of individual studies that reported information on the clinically relevant outcomes of overall and disease-free survival. Most studies pertained to patients who had received previous cytotoxic chemotherapy. These observations are in accordance with guidance provided recently by ASCO, the Food and Drug Administration (FDA), and the European Medicines Agency (EMeA).

Although few studies were conducted in the first line setting, for all outcomes and particularly for treatment failure, the predictive ability of *KRAS* mutations was lower compared to that observed in pre-treated patients. This observation argues for the need for further studies in the first line setting.

Regarding the two different agents, cetuximab and panitumumab, the predictive ability of *KRAS* mutations appeared to be similar. However, the bulk of available evidence for this comparison was related to studies assessing panitumumab as monotherapy in patients pre-treated with cytotoxic chemotherapy.

Variations in *CYP2D6* and response to tamoxifen in breast cancer

There were no consistent associations between *CYP2D6* polymorphisms and outcomes in tamoxifen treated women with breast cancer across 13 studies included in the systematic review.

The included studies were generally small in size, followed poor analytic practices, and differed both in the direction and in the formal statistical significance of their results. It is unclear whether pharmacogenetic testing of germline (heritable) mutations in *CYP2D6* can predict differential response to adjuvant tamoxifen in women with non-metastatic breast cancer.

Further, evidence is severely limited for tamoxifen-treated women with metastatic disease. Our conclusions

are in accordance with the 2009 American Society of Clinical Oncology practice guideline update.

We documented extensive heterogeneity in the definitions of *CYP2D6*-derived metabolizer categories across eligible studies. Determining the clinically meaningful genetic comparisons in a multi-allelic system is challenging, and may offer opportunities for data dredging. Most studies were relatively small and thus underpowered to detect what would be a plausible effect size for the modification of response to tamoxifen by a single polymorphism.

We found no evidence on whether patient or disease relevant factors affect the association between *CYP2D6*-derived metabolizer status and outcomes in tamox treated women. Such evidence would be obtained by examining interaction effects between the factors of interest and metabolizer status. However, no study performed such analyses. Several studies performed simple adjustments for patient level factors. This is not only noninformative, but also questionable from an analytic standpoint.

Variations in *BCR-ABL1* and response to imatinib, dasatinib and nilotinib in chronic myeloid leukemia

We identified 31 eligible studies. The presence of any *BCR-ABL1* mutation does not appear to predict differential response to treatment in CML patients treated with imatinib-, dasatinib-, or nilotinib-based regimens.

There is consistent evidence that presence of the relatively rare T315I mutation can predict TKI treatment failure, mainly in terms of hematologic and cytogenetic response. In contrast, there is no evidence that that presence of *any BCR-ABL1* mutation can differentiate response to TKI therapies.

The latter result is emblematic of the complexity of this topic: different mutations may confer different resistance to each of the three drugs. Exploring such relationships with systematic reviews of published aggregate data is extremely challenging. Other approaches, including collaborative registries of CML patients are much better suited to address such questions. Further, the majority of evidence pertains to the short term surrogate outcomes of hematologic, cytogenetic or molecular response.

Data on overall or progression-free survival are sparse. Finally, most evidence is on second line TKI treatments, especially dasatinib and nilotinib, and originates from a small number of referral cancer centers where those agents were first-tested before becoming more widely available.

The report is posted at http://www.ahrq.gov/clinic/ta/pharmgentest.pdf

Androgen Deprivation Therapy For Prostate Cancer May Raise Risk Of Cardiovascular Events

By Paul Goldberg

Androgen deprivation therapy for prostate cancer may increase the risk of cardiovascular events, warned a group of voluntary organizations and professional societies involved in treatment of prostate cancer and heart disease.

The "science advisory" to physicians and the public was published by the American Cancer Society, the American Urological Association, the American Heart Association, and the American Society for Radiation Oncology said patients receiving ADT should be monitored for signs of heart disease.

The advisory was published in the ACS journal CA: A Cancer Journal for Clinicians, and the AHA journal Circulation.

Patients should be evaluated for potential cardiac problems within three to six months following initiation of ADT, the health groups said. However, "there are no data to guide at what intervals periodic further follow-up should occur, and this is left to the discretion of the physician initiating ADT and to the patient's primary care physician," the paper states. "It does seem reasonable, however, that for men being treated with long-term ADT, blood glucose lipids should be checked at least yearly."

The paper cites several studies that point to harm from prostate cancer treatment, particularly a paper by H.K. Tsai et al, published in the Oct. 17, 2007, issue of JNCI, which reported that men over age 65 who were treated with hormones and radical prostatectomy were more likely to die of cardiovascular events than men treated with surgery alone.

Among men treated with surgery and hormones the five-year cumulative incidence of cardiovascular death was 5.5% (95% CI = 1.2% to 9.8%), compared to 2.0% (95% CI = 1.1% to 3.0%) in men treated with surgery.

"Patterns of care studies show that nearly a third of all American men diagnosed with prostate cancer recieve hormonal therapy for their disease at some time during their treatment," said Otis Brawley, ACS chief medical officer. "The take-home message from this paper is that the tendency to use hormonal therapy when its not needed can be harmful."

To Cut Colon Cancer Deaths, Reduce Barriers To Screening, NIH Consensus Panel Says

Colorectal cancer deaths could be reduced if barriers to screening were eliminated, a consensus development panel said in a draft report to NIH.

Colorectal cancer is the second leading cause of cancer-related deaths in the U.S. Despite evidence and guidelines supporting the value of screening for this disease, rates of screening for colorectal cancer are consistently lower than those for other types of cancer, particularly breast and cervical. Although the screening rates in the target population of adults over age 50, have increased from 20-30 percent in 1997 to nearly 55 percent in 2008—the rates are still too low, the panel said.

"We recognize that some may find colorectal cancer screening tests to be unpleasant and time-consuming. However, we also know that recommended screening strategies reduce colorectal cancer deaths," said Donald Steinwachs, panel chair, and professor and director of the Health Services Research and Development Center at the Johns Hopkins University. "We need to find ways to encourage more people to get these important tests."

The panel found that the most important factors associated with being screened are having insurance coverage and access to a regular health care provider. Their recommendations highlighted the need to remove out-of-pocket costs for screening tests.

Given the variety of tests available, the panel emphasized that informed decisions incorporating personal preferences may help reluctant individuals determine which test's combined attributes—invasiveness, frequency, and required preparation—are preferable to them, helping them identify and obtain the most palatable test. For example, an individual may choose a more invasive test requiring less frequent follow-up or a less invasive test requiring more frequent follow-up.

Noting differences in screening rates across racial and ethnic groups, socioeconomic status, and geographic location, the panel emphasized the need for targeted strategies for specific subgroups. Compared with non-Hispanic whites, Hispanics are less likely to be screened.

The panel also noted that if efforts to increase utilization are successful, there will be a greater demand for colorectal cancer screening services. Available capacity involves not only facilities and appropriately trained providers, but also support for informed decision making, resources to coordinate screening services and communicate results effectively, and enhanced monitoring practices to ensure that positive results are followed up with colonoscopy. Depending on the scale of increases in screening rates, there may be a need to increase local and national capacity.

In addition to increasing first-time screening rates, the panel also identified the need to ensure that individuals return for subsequent testing at the recommended intervals. A variety of colorectal cancer screening tests are available and different guidelines recommend them at different intervals.

The panel's statement is posted at http://consensus.nih.gov.

In addition to the material presented at the conference by speakers and the comments of conference participants presented during discussion periods, the panel considered pertinent research from the published literature and the results of a systematic review of the literature. The systematic review was prepared through the Agency for Healthcare Research and Quality Evidence-based Practice Centers program, by the RTI International-University of the North Carolina Evidence-based Practice Center. The EPCs develop evidence reports and technology assessments based on rigorous, comprehensive syntheses and analyses of the scientific literature, emphasizing explicit and detailed documentation of methods, rationale, and assumptions.

The evidence report on enhancing use and quality of colorectal cancer screening is available at http://www.ahrq.gov/downloads/pub/evidence/pdf/crcuse/crcuse.pdf.

FDA News:

Tykerb Granted Accelerated Approval For Breast Cancer

FDA granted an accelerated approval for a new combination regimen using Tykerb (lapatinib) as a first-line, all-oral treatment for metastatic breast cancer.

The agent is sponsored by GlaxoSmithKline.

The accelerated approval of the Supplemental New Dug Application covers Tykerb in combination with letrozole for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.

Tykerb in combination with an aromatase inhibitor

has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer.

"This combination of Tykerb plus Femara is an example of advancing science and improving patient care," Paolo Paoletti, senior vice president, GSK Oncology R&D, said in a statement. "This regimen attacks two specific receptors that drive cancer growth. Women battling this disease now have the opportunity to delay the use of traditional cytotoxic-chemotherapy, which is an exciting possibility for them."

Tykerb is indicated in combination with Xeloda (capecitabine) for advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.

The accelerated approval was based on a double-blind, placebo-controlled study, which enrolled 219 women diagnosed with post-menopausal, HR-positive and HER2-positive metastatic breast cancer, women treated with lapatinib and letrozole experienced a 5.2 month increase in median progression-free survival (PFS) compared to women treated with letrozole alone.

The most common (greater than or equal to 20%) adverse reactions during treatment with Tykerb plus letrozole were diarrhea, rash, nausea and fatigue.

In the Cancer Centers:

Arizona Cancer Center Names Three To Endowed Chairs

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will spend three years at M. D. Anderson, beginning this summer. He will conduct two years of research and serve one year of clinical-surgical training and practice.

M. D. Anderson's first collaboration at Sheba involves a cooperative learning relationship with MSR: The Israel Center for Medical Simulation. MSR is the world's first all-embracing "virtual hospital," where health professionals learn from their mistakes in a safe environment while training against role-playing actors and real-life computerized mannequins. MSR will be sharing its expertise in simulation training with M. D. Anderson in a wide variety of clinical domains related to oncology.

ARIZONA CANCER CENTER appointed three researchers to endowed chairs made possible by a $5 million gift from the estate of Fenton Maynard of Phoenix. The gift also will fund two research endowments for cancer center members.

Appointed to the endowed chairs are: **Alison Stopeck**, director of the Clinical Breast Cancer Program; **Bernard Futscher**, professor of pharmacology and toxicology and scientific director of the genomics shared service; and **Arthur Gmitro**, co-director of the cancer imaging program.

Research to be supported by the Maynard Endowment will be conducted by: **Amanda Baker**, research associate professor of medicine at the University of Arizona College of Medicine and director, translational research for phase I and II therapeutic trials, and director, flow cytometry shared service; and **Patricia Thompson**, assistant professor of public health in the Mel and Enid Zuckerman College of Public Health.

SIDNEY KIMMEL COMPREHENSIVE CANCER CENTER at Johns Hopkins professor **Stephen Baylin** was awarded the Alfred G. Knudson Award in Cancer Genetics from NCI. The Knudson award recognizes a scientist who has made outstanding contributions to the field of cancer genetics.

Baylin and his lab have led the way in the emerging field of epigenetics. His work specifically focuses on mishaps in a cellular process know as DNA methylation. Baylin is the Virginia and D.K. Ludwig Professor for Cancer Research. He received the award and presented a seminar at the NCI Intramural Scientific Investigators Retreat on Jan. 7.

Also at the Kimmel center, biostatistician **Gary Rosner** was appointed professor of oncology and director of the Quantitative Sciences Program and Biostatistics/Bioinformatics Division.

UNIVERSITY OF NEW MEXICO CANCER CENTER member Robert Atcher was appointed director of the National Isotope Data Center. Atcher is a professor of pharmacy at Los Alamos National Laboratory and UNM. He will coordinate NIDC activities, including operation of the Isotope Business Office, coordination of production and processing activities and the development and coordination of a suite of community outreach efforts.

Created in 2009, the NIDC will be a virtual full-service organization to support all isotope development and production sites in the community supported by the Department of Energy Office of Nuclear Physics within the Office of Science. Atcher's research focuses on the use of radionuclides for the diagnosis and treatment of

cancer. He is the immediate past president of the Society of Nuclear Medicine and the former president of the SNM's Radiopharmaceutical Sciences Council.

CITY OF HOPE received a nearly $3.5 million award from NCI to investigate the genetic factors that lead some cancer survivors to develop second malignancies. **Smita Bhatia**, chair of the Department of Populations Sciences, will lead the study. The five-year grant will allow researchers to study genes that influence how the body deals with cancer treatment, such as metabolism of chemotherapeutic drugs and DNA repair following radiation therapy.

The grant, provided through the NCI's Office of Cancer Survivorship, also brings together the data and expertise of scientists at 147 medical centers around the world. Scientists already have reached about two-thirds of their goal for the study by recruiting 3,600 cases of pediatric and adult cancer survivors diagnosed with a second cancer and 3,600 survivors who have stayed cancer free.

Other investigators in this study include **Susan Neuhausen**, of City of Hope; **Mary Relling**, of St. Jude Children's Research Hospital; and **Lue-ping Zhao**, of the Fred Hutchison Cancer Research Center.

EPPLEY INSTITUTE for Research in Cancer at the University of Nebraska Medical Center professor **Gloria Borgstahl** was elected to a three-year term on the U.S. National Committee for Crystallography. The USNC/Cr represents U.S. crystallographers in the International Union of Crystallography through the National Academy of Sciences.

ROSWELL PARK CANCER INSTITUTE announced the appointment of **Irwin Gelman** as chair, Department of Genetics. Gelman has been with RPCI since 2003. His research focuses on therapies to target prostate cancer, and his work has appeared in more than 50 journals and periodicals.

PURDUE'S Oncological Sciences Center and the Indiana University Melvin and Bren Simon Cancer Center will share a five-year, $1 million grant from the Walther Cancer Foundation to exchange medical fellows, engineers and scientists for advancing cancer research.

The Walther Oncology Physical Sciences & Engineering Research Embedding Program will be launched through the IU-Purdue Cancer Care Engineering project to create opportunities for postdoctoral fellows to train in clinics and for medical fellows to work in Purdue laboratories as interdisciplinary cancer research teams.

Purdue and IU each will invest an additional $250,000 in the project. Project leaders at Purdue are **Julie Nagel**, managing director of the Oncological Sciences Center; **Joe Pekny**, interim head of industrial engineering and chemical engineering professor; and **Marietta Harrison**, associate vice president for research. Purdue's project partners include the colleges of Science and Engineering, the Purdue Center for Cancer Research, and the Office of the Vice President for Research. **Patrick Loehrer Sr**., the Kenneth Wiseman Professor of Medicine and interim director of the IU Simon Cancer Center, is leading IU's efforts in the partnership.

UNIVERSITY OF MINNESOTA Masonic Cancer Center tobacco researcher **Jian-Min Yuan** has been awarded an $8 million research grant from NCI.

The grant will be disbursed over five years and used by Yuan to continue epidemiological cancer research involving 81,500 middle-aged and older Chinese men and women enrolled in the cities of Shanghai, China and Singapore respectively. The goal of the research is to identify environmental and genetic factors that put people at risk for cancer. This grant also will support the development of an effective set of non-invasive markers that can be used to screen and identify people who are at high risk for lung or liver cancer.

Professional Societies:

ASTRO Commits To Greater Safety, Quality Of Patient Care

The American Society for Radiation Oncology has committed to a six-point patient protection plan that will improve safety and quality and reduce the chances of medical errors, ASTRO Board Chairman Tim Williams said.

"ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments by providing tools and professional guidance to our members," said Williams, a radiation oncologist at Boca Raton Community Hospital. "We have been developing and refining many of these programs for years and they have been making a huge difference in the quality of cancer treatment. By committing to this plan, we are redoubling our efforts in this essential area of our specialty."

Williams acknowledged that recent reports about

serious errors in the delivery of radiation therapy were deeply troubling to the society.

"In any area of medicine, and radiation oncology is no exception, even one error is too many," he said. "We have been a leader in efforts to improve the culture of radiation safety within our specialty. Any errors, no matter how small, must be reported, understood and used as a tool to further reduce the potential for future errors. ASTRO is committed to leading the way to helping physicians and treatment teams do just that."

ASTRO Board's Safety Plan

The plan from the ASTRO Board of Directors comes after a systemic review of the society's patient safety and quality assurance projects that began as part of the Board's winter meeting Jan. 28-31.

It includes:

1. Working with the Conference of Radiation Control Program Directors and other stakeholders to create a database for the reporting of linear accelerator- and computed tomography-based medical errors.

2. Launching a significantly enhanced practice accreditation program, and beginning the development of additional accreditation modules specifically addressing new, advanced technologies such as IMRT, SBRT and brachytherapy.

3. Expanding our educational training programs to include specific courses on quality assurance and safety, and adding additional content to other educational programs.

4. Working with patient support organizations to develop tools for cancer patients and caregivers for use in their discussions with their radiation oncologist to help them understand the quality and safety programs at the centers where they are being treated. These tools will include questions to ask their treatment team, such as, "Do you have daily safety checks?" and "What kinds of safeguards do you have to make sure I'm given the right treatment?"

5. Further developing our Integrating the Healthcare Enterprise – Radiation Oncology connectivity compliance program to ensure that medical technologies from different manufacturers can safely transfer information to reduce the chance of a medical error.

6. Providing our members' expertise to policymakers and advocating for new and expanded federal initiatives to help protect patients, including support for immediate passage of the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy (CARE) Act to require national standards for radiation therapy treatment team members; additional resources for the National Institute of Health's Radiological Physics Center to evaluate the safety of treatments; and funding for a national reporting database.

Institutes Plan To Develop Drug Safety Assessment Tool

The Institute for Safe Medication Practices, ISMP Canada, and the International Society of Oncology Pharmacy Practitioners said they will begin development of a new self-assessment tool to help hospitals and ambulatory cancer centers throughout the world evaluate oncology medication safety.

Chemotherapy agents used in cancer treatment are considered "high-alert" drugs, which are more likely to cause patient harm when involved in an error. The self assessment will help healthcare organizations examine the use of these medications by evaluating practices and processes related to patient information, communication, environment, and other key elements of safe medication use.

As with ISMP's previous self-assessments, healthcare organizations will be asked to convene multidisciplinary teams to complete the survey and submit data confidentially through a secure web-based form. Respondents will then be able to compare their results with aggregate data from other demographically similar organizations.

An international group of safety experts will be organized to assist with the development, design, and launch of the assessment, which is scheduled for early 2011.

The oncology medication safety self assessment is being supported through a grant from ISOPP to ISMP and ISMP Canada. The Clinical Excellence Commission, the Australian Commission on Safety and Quality in Health Care, and the Cancer Institute of New South Wales have also provided grant support and their expertise to this project. Private sector support was received from Baxter Corporation, ICU Medical, Inc., Pfizer Oncology, and Roche.