In 2018, SNMMI created the Value Initiative and Industry Alliance to advance nuclear medicine and molecular imaging. The strategic vision includes collaboration with industry, sister societies, our membership and others to showcase the crucial role of nuclear medicine and molecular imaging to the medical community, regulators, patients, and the public.

While our strategy and goals in R&D, Quality of Practice, Advocacy, Outreach and Workforce Pipeline are long-term, we have achieved key milestones in a short timeframe.

A small sample of these accomplishments in 2018-2019:

- **Quality of Practice**: Achieved 36 measurable outcomes, including completing three AUC: prostate cancer imaging, gastrointestinal transit scintigraphy, and evaluation and treatment of differentiated thyroid cancer, all of which have been submitted to JNM.

- **Outreach**: Achieved 20 key benchmarks, advancing patients’ and the medical community’s understanding of the value of nuclear medicine, molecular imaging and radionuclide therapy. Examples include holding a Patient...
There was a great deal of enthusiasm for radiopharmaceutical therapy evidenced by the sold-out SNMMI Therapeutics Conference: Therapies, Theranostics and Building your Radionuclide Clinical Practice in Las Vegas Nevada this past October. A superb group of speakers covered a wide range of topics from the basic nuts and bolts of starting and growing a radiopharmaceutical therapy practice through the nuances of medical management and the role of the authorized user as an integral member of the patient care team. This is of critical importance as therapeutic radiopharmaceuticals do not cleanly fit into existing cancer care workflows as the work up, delivery, toxicity, precautions are all distinct from chemotherapy and external beam radiotherapy. Thus, authorized users for therapeutic radiopharmaceuticals need to have the requisite specific training and knowledge, though authorized users can and should come from multiple backgrounds and must be capable of making treatment decisions.

While the authorized user must make treatment decisions and is responsible for the overall delivery of therapeutic radiopharmaceuticals, a nurse navigator or similar position can be an invaluable resource as a single point of contact amidst complex logistics. Furthermore, it is important to have champions of the treatments. At first glance, starting or growing a program may seem burdensome, but the champion must elucidate all of the patient benefits of these unique and efficacious treatments to counter the challenges. For example, radiation safety concerns must be considered in the context of patient benefit (as well as the real patient risks in the absence of life-extending treatment options). Armed with knowledge and expertise, radiopharmaceutical therapy teams that are integrated into patient care decisions can help to determine the most appropriate treatment for a given patient at a given time. When that best option is a radiopharmaceutical, they can lead the informed consent process, ensure appropriate coding and billing and provide a safe venue for treatment delivery as well as expert follow up so patients can optimally benefit.

The multi-disciplinary emphasis of the conference was an effective tool to give our diverse group of attendees a very well-rounded educational experience regarding the value of therapeutic radiopharmaceuticals when treating patients with neuroendocrine, prostate and thyroid malignancies. We sincerely appreciate our industry sponsors for giving the SNMMI the support necessary to provide high quality education that will help disseminate the latest data and best practices to a wide range of practices nationally and internationally. We eagerly look forward to expanding our partnerships with oncologists, technologists, physicists, radiopharmacists, administrators, and our industry partners as we incorporate these game changing tools into our patient facing nuclear medicine practices.
Providing Solutions Today, While Advancing the Practice of Nuclear Medicine, for Tomorrow

Our Radiopharmaceuticals and Radiopharmacies Divisions are Focused on Improving Lives Through Nuclear Medicine

JAMES KAUFMAN, VP, MARKETING, JUBILANT RADIOPHARMA™

Jubilant Radiopharma™ is an industry leading pharmaceutical company specializing in nuclear medicine. Our Radiopharmaceuticals and Radiopharmacies Divisions are focused on developing, manufacturing, commercializing and distributing high quality diagnostic and therapeutic agents for the sole purpose of Improving Lives Through Nuclear Medicine™ on a global scale.

We are committed to advancing the utility of nuclear medicine through research and drug development. Our expert team is working to build the most robust product pipeline of generic and next generation radiodiagnostics and radiotherapeutics in the industry. These new products will help enable early and accurate diagnosis and treatment of disease, ultimately leading to better patient outcomes.

Our state-of-the art cGMP manufacturing facilities are staffed by highly skilled technical personnel, who are dedicated to providing high quality and reliable products to healthcare professionals around the world. They are unwavering in their efforts to produce the most cutting-edge technologies and superior services, so our customers can feel secure knowing every step is taken to assure the integrity and dependability of our products.

We have assembled a team of experts from across the industry, who work tirelessly to advance the utility and expansion of nuclear medicine.

Our global regulatory filing experts, international sales teams, accomplished medical staff, and reimbursement support teams allow us to bring new targeted theragnostics to the market faster, which helps us provide even greater access to best-in-class products to healthcare professionals and their patients.

Our expanding radiopharmacies network is staffed by board certified pharmacists and technologists. Quality is at the core of everything we do. Our team procures, prepares and delivers the highest quality FDA-approved products. We fully support USP compounding standards and prepare the exact dose requested in compliance with all state and federal regulations to ensure delivery where it is needed, when it’s needed. This allows our customers to focus on the care of their patients.

We are continually working to expand our infrastructure and develop our people to better provide the nuclear medicine community with customized solutions that combine the clinical expertise of a global manufacturer with the local reach of a leading pharmacy network; to support our customers today, while advancing the practice of nuclear medicine, for tomorrow.

An article by Jubilant Radiopharma™, a SNMMI Value Initiative Industry Alliance Leadership Circle Partner.
The Targeted Radionuclide Therapy Conferences have been a combined effort of SNMMI, NCI, and the FDA for the past two years. Recently the third conference was held at the NCI Shady Grove facility on December 16, 2019. The theme of this year’s conference was “What is the goal with radionuclide therapies - palliative, curative, or adjuvant treatment?”. All major stakeholder groups were robustly represented in the nearly standing room only venue. Participants included senior FDA officials, pharmaceutical company executives, NCI officials, and academia.

The full day of lectures and discussion was divided into four sessions that migrated over the course of the day from the basic underlying science of targeted radionuclide therapies both in terms of the physics and radiation biology, through clinical trial design strategies, and finally strategies toward achieving and measuring clinical response.

On the basic science side, the challenge associated with the physical and biological complexities associated with alpha-emitting decay chains was presented. Stunning alpha-camera images of the kidney were displayed demonstrating the necessity of microdosimetry to truly understand biological effects. Other presentations summarized current state-of-the art image-based dosimetry applications, including their current capabilities and limitations on quantitation. The concept of applying the quantitative paradigms of external beam radiation therapy (like Dose-Volume Histograms) to TRT was convincingly presented.

Trial design talks summarized the current status of Phase 1 and Phase 2 theranostic trials in the US, Australia, and Germany. The regulatory approaches of the three countries vary

Value Initiative 2.0 Continued from page 1.

Education Day, educating 80 patients, caregivers and advocates; and conducting ten regional CME roadshows on NETs and sentinel lymph node mapping, educating more than 300 medical professionals.

• **R&D:** Achieved 27 key benchmarks, including completing the ‘Mars-Shot’ for Precision Molecular Imaging and Molecular Radiopharmaceutical Therapy, detailing the possibilities of MI; creating an AI Task Force; establishing grants for NM/MI research by medical or science students; and completing two NCI Targeted Radionuclide Therapy Consensus Conferences with more than 250 expert participants.

• **Advocacy:** Achieved 14 major milestones in health policy and regulatory affairs, including leading and participating in two major legislative fly-ins with SNMMI doctors and patients and conducting more than 100 Congressional office visits, which helped secure ten co-sponsors for the bipartisan Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2019 (HR 3772).

• **Workforce Pipeline:** Achieved 18 success indicators, including creating a comprehensive database of residency training programs for all diagnostic radiology/nuclear radiology/nuclear medicine residents and fellows with thousands of new residents identified and offered SNMMI membership/training.

SNMMI is the oldest and most prestigious nuclear medicine and molecular imaging society worldwide. With 3 centers of excellence, 10 councils and 14 chapters, SNMMI has a robust governance structure underpinning the Value Initiative strategy.

As we enter 2020, SNMMI builds on its 2018 and 2019 success with **Value Initiative 2.0** and three goals:

• Empower all members via councils/centers/chapters.
• Increase collaboration with providers and medical societies.
• Increase awareness of NM/MI in general public.

Within these strategic goals, VI 2.0 will advance the field’s innovation by:

• Creating theranostics practice and training,
• Continuing to advocate for appropriate reimbursement
• Filling gaps identified in NM/MI research,
• Providing research funding for trainees,
• Expanding AUCs with care pathway strategy,
• Engaging hospitals and payors
• Creating a framework for MI and population management
• Increasing diversity and empowering WINM
• Creating a more robust leadership program

This is an exciting time for nuclear medicine and molecular imaging. New therapies and imaging agents are transforming the field, helping nuclear medicine professionals improve patients’ lives. This is the time to aggressively invest in strategies that make a difference for patients.

We sincerely appreciate our partnership to advance the value of nuclear medicine and molecular imaging.

Satoshi Minoshima, MD, PhD
Chair, SNMMI Value Initiative 2.0
Professor and Anne G. Osborn Chair
Department of Radiology and Imaging Sciences
University of Utah, Salt Lake City, UT
In May, 2016, the US. Food and Drug Administration approved Blue Earth Diagnostics’ Axumin® (fluorine 18) injection for use in PET imaging of recurrent prostate cancer. As the first F-18 PET imaging agent approved for this purpose, Axumin is an innovative nuclear medicine product that has since been included in major clinical guidelines supporting its use as an imaging option for prostate cancer recurrence or progression. Since approval, Axumin coverage has grown to include more than 145 million commercially insured lives and is covered by all Medicare Administrative Contractors (MACs). The efficacy of Axumin was established in two clinical studies. Published results from the LOCATE trial demonstrated that Axumin scans affected clinical management decisions in 59% of patients with recurrent prostate cancer, with 78% of those changes considered to be major such as a change in treatment modality. Axumin has changed disease management for many recurrent prostate cancer patients.

The Centers for Medicare and Medicaid Services (CMS) designed the transitional pass-through model to ensure appropriate payment for innovative new products by paying separately for them for up to three years. After the transitional pass-through period expires, diagnostic radiopharmaceutical payment is bundled with the payment for the procedure. On January 1, 2020, Axumin, along with other PET radiopharmaceuticals, lost its pass-through designation with CMS. This has left hospitals with the unfortunate choice to perform these scans on Original Medicare beneficiaries at a significant loss or to discontinue the service upon which patients and physicians have come to rely.

The last quarter of 2019, Blue Earth Diagnostics reached out to more than 250 U.S. hospitals to assess the potential impact of loss of pass-through payment on patient access to Axumin. These institutions spanned academic and community hospitals and included both for-profit and not-for-profit hospitals, all facilities use the Hospital Outpatient Prospective Payment System (HOPPS) for billing. The objective of the survey was to determine the effect of loss of pass-through on Axumin use in a given institution. Although results were mixed, the overarching conclusion was that there will be a significant number of patients who will not receive Axumin who may have otherwise benefited from its use.

Results indicated that:

- 53% of respondents are unsure whether they will offer Axumin PET scans with the loss of pass-through payment in the hospital setting;
- 25% indicated they will not continue to use the product with the loss of pass-through payment; and

Continued on page 8. See Innovative
When industry, academia, the U.S. government and scientific and professional societies share a common vision to address a medical supply need, the results can benefit patient healthcare. Such was the case in securing a reliable domestic supply of molybdenum-99 (Mo-99), the parent isotope of technetium-99m (Tc-99m), for the United States. Tc-99m is the most widely used imaging radioisotope. When used in conjunction with FDA-approved cold kits, Tc-99m is used to help diagnose and stage serious medical conditions such as heart disease, cancer, infection and inflammation. Tc-99m radiopharmaceuticals represent the standard of care for cardiac imaging, which represents approximately 55-60% of the 40,000 Tc-99m imaging procedures performed daily in the United States.

For decades prior to 2018, the United States was dependent on importing Mo-99 produced using highly enriched uranium. In light of frequent and sometimes prolonged Mo-99 supply interruptions impacting the availability of Tc-99m for U.S. patients’ imaging procedures, and out of national security concerns about the use of highly enriched uranium in producing Mo-99, the U.S. government, industry and scientific and professional organizations took action. Legislation was enacted, technology development incentives were implemented and companies sought solutions. One company, NorthStar Medical Radioisotopes, a global innovator in the production and distribution of radioisotopes used for medical imaging, recognized the challenges faced by nuclear medicine in obtaining secure and reliable radioisotope supply, and worked to develop commercial applications in partnership with other organizations.

The first success of collaborative efforts to establish U.S. Mo-99 production to help minimize reliance on highly enriched uranium-based supply came when the FDA approved NorthStar’s novel technology, the RadioGenix® System, which elutes Tc-99m from domestically produced non-uranium based Mo-99 sources. As a result, U.S.-produced, non-uranium based Mo-99 is now available, helping to alleviate ongoing Tc-99m supply shortages. Radiopharmacies using NorthStar technology have had access to more than 12 months of uninterrupted Tc-99m supply, despite consistent supply shortages due to issues with uranium-based Mo-99 production. The RadioGenix® System is an innovative high tech radioisotope separation platform for use in producing Tc-99m from non-uranium based Mo-99.

Various agencies across the U.S. government played instrumental roles in the project’s success, particularly the Department of Energy’s National Nuclear Security Administration (DOE/NNSA). Through its cooperative agreement program, the DOE/NNSA partners with industry and brings U.S. government resources to bear in addressing issues around national security and medical isotope supply. The objective of its efforts is to establish reliable supplies of Mo-99 to meet U.S. patient needs for Tc-99m, while advancing U.S. nuclear nonproliferation policy by eliminating the use of proliferation-sensitive highly enriched uranium in medical isotope production around the world. DOE/NNSA has partnered with NorthStar and provided funding to accelerate its efforts. DOE/NNSA has also made available technical expertise and specialized facilities at the National Laboratories to advance development of the company’s technology. Additionally, the FDA and Nuclear Regulatory Commission worked alongside NorthStar in providing guidance throughout the process.

Partnerships with academic institutions can be critical in developing continued on page 8. See Domestic Radioisotope.
Innovative Continued from page 6.

- 22% will most likely continue to use Axumin regardless of its pass-through payment status.

In 2019, the Medicare Diagnostic Radiopharmaceutical Payment Equity Act (H.R. 3772) was introduced in the U.S. House of Representatives to preserve Medicare beneficiary access for certain diagnostic radiopharmaceuticals under the Medicare hospital outpatient prospective payment system. Our industry is dedicated to supporting patient access to innovative nuclear medicine products today and in the future. Therefore, we urge you to reach out to your members of Congress in support of H.R. 3772.

Members of Congress are particularly interested in hearing about your personal experience and how the loss of pass-through will impact you and your patients rather than simply receiving numerous pre-written letters. You can email your members of Congress directly, or you can edit the suggested letter(s) linked here before submitting.

- www.rightscanrighttime.org/act_pet

Axumin® (fluciclovine F18) Injection Indication

Axumin injection is indicated for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment.

Axumin® (fluciclovine F18) Injection Important Safety Information

- Image interpretation errors can occur with Axumin PET imaging. A negative image does not rule out recurrent prostate cancer and a positive image does not confirm its presence. The performance of Axumin seems to be affected by PSA levels. Axumin uptake may occur with other cancers and benign prostatic hypertrophy in primary prostate cancer. Clinical correlation, which may include examination of tissue samples, is recommended.
- Severe allergic reactions, including anaphylaxis, may occur in patients who receive Axumin. Emergency resuscitation equipment and personnel should be immediately available.
- Axumin use contributes to a patient’s overall long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Safe handling practices should be used to minimize radiation exposure to the patient and health care providers.
- Adverse reactions were reported in ≤1% of subjects during clinical studies with Axumin. The most common adverse reactions were redness and pain at the injection site, and an unusual taste in the mouth.

To report suspected adverse reactions to Axumin, call 1-855-AXUMIN1 (1-855-298-6461) or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. Full Axumin prescribing information is available at: www.axumin.com.

1. Referenced with permission of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer: Version 2.2018. © National Comprehensive Cancer Network, Inc. 2018. All rights reserved. Accessed 03/30/2018. To view the most recent and complete version of the guideline, go to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
3. An article by Blue Earth Diagnostics, A Bracco Company, a SNMMI Value Initiative Industry Alliance Leadership Circle Partner.

Domestic Radioisotope Continued from page 7.

Radioisotope technology. Beginning in 2009, NorthStar worked in collaboration with the University of Missouri Research Reactor (MURR®), the highest-power university research reactor in the United States. With a shared vision to alleviate radioisotope supply shortages and advance research, NorthStar and MURR refined and developed Mo-99 production technology based on stable molybdenum rather than enriched uranium. With neutron capture technology, the isotope Mo-98 is irradiated to form Mo-99. Neutron capture avoids potential national security and environmental concerns associated with enriched uranium.

Through advocacy and outreach, scientific and professional organizations such as SNMMI encouraged development of new technologies and domestic production facilities to secure reliable domestic Mo-99 supply. Educational programs and support for technology innovation help advance the role of nuclear medicine to the medical community, regulators, patients and the public.

As seen in this case of U.S. Mo-99 supply, effective collaboration combined with well-executed technology development can help advance concepts into real-world solutions to benefit patient healthcare. With FDA approval and commercial availability, NorthStar’s initial technology success is translating into ongoing expansion, development of increasingly efficient radioisotope production using neutron capture and accelerator technologies and research to produce additional radioisotopes. New production technologies will enable the United States to diversify the means of Mo-99 production so that industry is no longer reliant solely on a technology with its acknowledged limitations and risks. Through the efforts of companies like NorthStar Medical Radioisotopes working in partnership with government, academic institutions and professional societies, the future for U.S. radioisotope supply to meet patient and research needs appears dynamic and promising.

2. As of January 1, 2017, all local MACs confirmed that Axumin is covered for its label indication. Please check with the MAC that covers your Medicare patients to determine their specific coverage policies.

An article by NorthStar Medical Radioisotopes, a SNMMI Value Initiative Industry Alliance Corporate Member Partner.
substantially, largely due to differing guiding philosophies. Australian Therapeutic Goods Administration (ATGA) recognizes the tracer mass levels associated with PET drugs and therapeutic drugs and allows for local hospital-level regulation of radiopharmaceutical use for experimental agents. Sites must inform ATGA about the research. This has enabled rapid adoption and testing of radiopharmaceuticals in Australia. In turn, Australia created a clinical trial network made up of multiple academic sites throughout the country. ARTNet has facilitated well-designed, prospective, randomized trials that will very likely demonstrate the clinical efficacy of the theranostic approach. The German approach is markedly different and allows early trials in humans, under local authority and for compassionate use and does not require approval of the equivalent of an FDA IND. However, this arrangement does not allow the use of these agents in properly designed prospective clinical trials and explains why almost all of their studies are retrospective, non-randomized and without tightly controlled inclusion and exclusion criteria. The US approach is inherently longer, involving Phase 1 studies first to demonstrate safety, followed by phase 2 studies to demonstrate efficacy. Although there are a number of NCI funded clinical trial groups (SWOG, COG, ECOG-ACRIN, NRC, and Alliance) there is currently no effort in the US that is similar to the Australian approach, although the model appears to be an enticing one to mimic.

The FDA discussed the regulatory considerations particularly relevant to theranostics. While it is possible to get both the diagnostic and therapeutic agents approved simultaneously, it is easier and often more practical to get the diagnostic agent approved first. Examples were given for a PD-L1 blocker with testing for PDL-1 status of tumors and for Ga68 DOTATATE and In111 Octreotide. The FDA speakers emphasized the need to contact the FDA early and often during the drug development/approval process to maximize speed and efficiency of the process. Look for the proceedings of this meeting to be published in the near future.
SNMMI’s Volunteer Leaders and Industry Partners Play an Indispensable Role in the Progress and Success of SNMMI Value Initiative Efforts

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- Dose Optimization Task Force
- Oversight Committee for Guidance Documents
- Quality and Evidence Committee

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- Committee on Radiopharmaceuticals
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- CMIIT

Domain 3: Workforce Pipeline
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- Future Leaders Academy Task Force
- Academic Council
- Program Directors Committee
- Qualified Training Program Task Force
- Committee on Young Professionals

Domain 4: Outreach
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- Targeted Radiosotope Therapy Working Group
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SNMMI’s Volunteer Leaders and Industry Partners Play an Indispensable Role in the Progress and Success of SNMMI Value Initiative Efforts
SNMMI would like to thank our Value Initiative Industry Alliance Member Companies:

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