Taking Molecular Imaging Development to the Next Level

The pharmaceutical imaging development community has continued to experience challenges in the development of safe and effective new imaging agents. The imaging community has expressed widespread agreement that imaging biomarkers can facilitate more efficient drug development and faster deployment of approved, life-saving therapies. The U.S. Food and Drug Administration (FDA) Critical Path Initiative (CPI) has responded to these challenges for imaging and to the community's need to move the development of imaging forward in concert with new therapeutics.

The CPI seeks to identify and address scientific and technical challenges to the optimum development of safe and therapeutically important medical products. Development of standard protocols for validating and using medical imaging as a biomarker in therapeutic product development is a priority of the CPI and has been highlighted under opportunities 21–28 in the Critical Path Opportunities List (www.fda.gov/oc/initiatives/criticalpath/reports/opp_list.pdf).

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Within the CPI, FDA is pursuing collaborations with multiple parties through effective pooling of expertise and resources to find constructive and innovative ways of reducing the development time required to bring new and therapeutically important medical imaging drug and biologic products to the market and to ensure the safety of these medical imaging products.

Because of the opportunity that the CPI represents, SNM leaders have taken a bold step to jumpstart the process of bringing new imaging agents to market. In May, SNM began working with FDA to define the best

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ABMS: What Is It, and Why Should I Care?

Why is it important to know about the American Board of Medical Specialties (ABMS)? The ABMS is the umbrella organization for the 24 primary boards. In the past, the member boards were quite independent, and ABMS primarily provided a convenient structure through which boards could discuss common problems and goals. In the future, boards will become less independent. ABMS will be establishing more standards with which each of its member boards must comply. It is important to know about the ABMS because it will increasingly affect our professional lives.

Why is this happening now? Two seminal reports from the Institute of Medicine raised concerns about patient safety (*To Err is Human: Building a Safer Health System* [2000]) and the quality of healthcare (*Crossing the Quality Chasm: A New Health System for the 21st Century* [2001]). These reports have sparked great interest in improving patient safety and the quality of health care.

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ABMS intends to play a more central role in assuring the public about the quality of health care provided by specialists. The ABMS would like to be one of the primary physician groups with significant input into future changes in health care and is in a unique position to do so for 2 reasons. First, ABMS is not a specialty society in which policies are determined by physician members; instead, its main mission for the last 75 y has been to assure the public that board-certified physicians were competent in their specialty. The ABMS has a number of new initiatives intended to increase public trust in its

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opportunities for constructive partnerships to improve the development of imaging. It was agreed that the first goal would be for SNM to file an investigational new drug (IND) application for ^{18}F-fluorothymidine (^{18}F-FLT). This SNM-sponsored centralized IND allows therapeutic developers to cross-reference the IND to enable use of the investigational PET imaging agent in multicenter clinical trials. SNM's centralized IND was approved by the FDA in September. This IND serves as proof-of-concept for the development of a multicenter clinical trial pathway to move ^{18}F-FLT and other existing and future diagnostic imaging biomarkers out of the lab and into clinical trials use.

FDA has made it clear that a significant challenge of imaging-based multicenter clinical trials has been a lack of standardization in technology capability, imaging protocols, and biomarker manufacturing practices. A goal of working with FDA is to jointly create imaging protocols that ensure that all participants in trials follow a standardized imaging protocol and that imaging results are evaluated consistently.

FDA is aware that SNM has worked hard to engage NCI pharmaceutical companies, academia, patient groups, professional organizations, and other stakeholders in the SNM Molecular Imaging Clinical Trials Network to successfully interact with FDA. I am proud to be a part of this process that builds effective working platforms and strong bridges between all of these groups, and I anticipate that the community will gain great benefits in patient care and patient safety.

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activities. Second, 85% of physicians are certified by 1 or more of its primary care boards, so ABMS has a greater influence than most physician organizations.

If the ABMS and its boards are to assume a leadership role in improving the quality of health care, maintenance of certification (MOC) must have greater standardization between boards. Each board currently has designed and implemented its own MOC program with some guidance from ABMS. In the future, ABMS will require all boards to include certain elements in their MOC programs. An example of such a new requirement is that all boards will have to require their diplomates to complete a module on patient safety. A stronger ABMS will result in some loss of autonomy for individual boards but ultimately should increase the value of board certification. More information about the ABMS is available at www.abms.org.

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DC) and a nuclear medicine consultant to the National Institutes of Health (NIH) Clinical Center (Bethesda, MD). From 1992 to 1995, he was chief of the NIH Radiopharmaceutical Research Section and consulted in the Clinical Center until retiring in 1996.

McAfee served on numerous committees for NIH and the National Academy of Sciences. He was named a most frequently cited author of papers in *Radiology* for the years 1955–1986. A prolific writer, he was the author or coauthor of more than 300 papers, book chapters, and abstracts. He held more than 20 U.S. and Canadian patents for bone-seeking ^{99m}Tc complexes and ^{99m}Tc-stannous imidodiphosphonates.

The scientific community recognized his pioneering work with numerous honors and awards. In addition to his gold medal award from the RSNA in 2004, he delivered the Diamond Jubilee Lecture on "Nuclear Medicine Comes of Age: Its Present and Future Roles in Diagnosis" at RSNA in 1989. The SNM honored him with the Georg Charles de Hevesy Nuclear Medicine Pioneer Award and the Paul C. Aebersold Award. Other honors included the Herrmann L. Blumgart Award from the New England Chapter of SNM and the Johns Hopkins Alumni Award in Nuclear Medicine.

Many of his colleagues have noted that he was an excellent clinician and a very compassionate human being. I personally can attest to both. In the late 1970s, my brother was fighting an ultimately fatal illness. I would occasionally go to Syracuse where he was hospitalized at critical points in his care. John always provided access to the nuclear medicine group with instructions to show me good cases to take my mind off my situation while waiting for some clinical news about my brother. He also came down to further distract me and to ensure that there was good clinical discussion about each case.

When I was made editor-in-chief of the *Yearbook of Nuclear Medicine* in 1995, I asked John to be an associate editor. For the next few years (until the editorial process was reorganized and he chose to no longer continue), his editorial thoughts were superb. When colleagues commented about the yearbook and I was hoping for some personal recognition, what I usually got was: "Good job—McAfee's comments are terrific!" I always thought this encapsulated John McAfee's intellectual curiosity, his extensive knowledge (he was an avid reader), and his scientific insight.

In addition to his professional accomplishments, McAfee was an avid sailor and organist. Survivors include his children, Paul C. McAfee, Carol J. McAfee, and David R. McAfee, and 5 grandchildren.

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