

SCANNER

THE OFFICIAL NEWSLETTER OF THE ACNP

Editor-in-Chief: Simin Dadparvar, MD

Associate Editor: Ann Coleman

March, 2004

President's Message



As the incoming President of the College, I must start by saying that I am most fortunate to be arriving on the scene at this time. A number of people have worked very hard over the last several years to reinvigorate the American College of Nuclear Physicians, and the fruits of their efforts were obvious to all who attended the recent 30th anniversary meeting of the College in Marco Island, Florida. Since the glamorous 25th anniversary meeting in Hawaii, we have met in conjunction with the Society of Nuclear Medicine and the American College of Nuclear Medicine. While those meetings gave us opportunities that would not have otherwise been available, it was great to be back on our own. The venue was beautiful and the meeting itself held the attention and the

presence of the registrants through the morning-only sessions. Opening the afternoons to relaxation and family time was a well-received innovation, introduced by Dr. Dadparvar. The return of resident presentations was similarly well received. I want to thank all of the presenters, for their cooperation and participation. We look forward to similar successes at the 2005 meeting next winter on the West Coast.

Though the success of the annual meeting was the most obvious manifestation, there are other ongoing activities that point to the turnaround in the College's vitality. Outside of the lecture hall, a number of meetings were held to identify both general directions and specific tasks for all of us. The current elected leadership was joined by a number of past president's for a Leadership Council. This event yielded a long list of goals, some of which are to be immediately implemented and others that will be a focus for our energies in the relative near-term of the next several years. While I appreciate the need for longer-term strategic planning, I was particularly pleased by the way our facilitator, Dr. Sue Wallace, kept our feet fixed on the ground of reality. We have work to do now.

While we are the masters of our own destiny in some areas, we recognize that we are just one of the many professional, commercial, and governmental players in the imaging scene. We will actively pursue alliances with our friends and deal as we can with the others. The College is most fortunate to have the continued support of two very important partners in the field. The leadership of the Society of Nuclear Medicine have expressed their willingness for us to take on an important role in the challenges we both face. The Society and the College already cooperate on the Government Relations Committee, but there are numerous opportunities for the College to expand its impact in other areas. In that regard, meetings have been held with leaders in the nuclear medicine industry. Historically an integral part of the College, industry representatives have made it clear that they are eager to support our activities, but we must

demonstrate our willingness and ability to hold up our end of the projects. Industry support was important in the success of the annual meeting, and we hope to quickly demonstrate our expertise in such projects as the Physician Outreach Program and other activities that are jointly recognized by the College and industry as advantageous to the field of nuclear medicine.

In planning for the next year and beyond, the College is surely “blessed” with a number of challenges and opportunities. Dr. Dadparvar in particular and a core group of other members have worked tirelessly over the last year to place the College on solid footing. They are committed to continuing their involvement, but we must also continue to expand the body of involved members. Some of you will be contacted directly to solicit your assistance on committees and projects, but, as is true for most volunteer organizations, the number of potential projects far exceeds the number of volunteers. All are welcome. I will gladly receive a phone call from any member who has a suggestion or a request. I would especially appreciate phone calls from those of you who wish to volunteer your service in a specific project or “as needed.” Together, organized nuclear medicine has some unique and valuable strengths, but without grassroots involvement to supplement the work of the collective organizations’ elected leaders and our most capable central office staff, the specialty of nuclear medicine will not be able to reach its potential.

*Warren Moore, MD, FACNP
President, ACNP*

ACNP Scientific Program Award Winners

The ACNP Scientific Program awards were announced in January at the 30th Annual Meeting of the ACNP in Marco Island, Florida.

Congratulations to:

1. **Rakesh Kumar, MD** from Hospital of University of Pennsylvania, who was awarded a \$750 Travel grant for the abstract, “Evaluation of Adrenal Mass in Patients with Cancer Using 18F-Fluorodeoxyglucose Positron Emission Tomography.”
2. **Irini Youssef, MD** from St Vincent Medical Center in New York, who was awarded a \$750 Travel Grant for the abstract, “Incidence of Nonsentinel Lymph Node Involvement in Breast Cancer (BR CA) in Presence of Macro or Micro Metastatic (METS) Involvement of Sentinel Lymph Nodes (SN).”
3. **Jian Q. Yu, MD** from the Hospital of University of Pennsylvania, who was awarded a \$500 best assay award for the abstract, “Detection of Recurrent and Metastatic Head and Neck Cancer with FDG-PET in comparison to CT or MRI.”
4. **Marsha Nydich, MD** from the St. Luke’s-Roosevelt Hospital in New York, who was awarded a \$500 best assay award for the abstract, “Incidental Findings on Whole Body FDG PET Scans are Frequently Due to Malignant or Premalignant Conditions.”
5. **Ghessan El-Haddad, MD** from the Hospital of University of Pennsylvania, who was awarded a \$500 best assay award for the abstract, “Indium-111-Labeled Octreotide Scintigraphy in Restaging of Somatostatin Receptor-Rich Malignancy.”

Manuscript Submission Deadline Extended to March 15

All participants, regardless of award status are encouraged to submit their manuscripts for consideration for publication in the *Journal of Nuclear Medicine* **no later than March 15, 2004** to the following address:

Ms. Jennifer Morse
American College of Nuclear Physicians
1850 Samuel Morse Drive
Reston, VA 20190

Submitted manuscripts will be pre-screened and reviewed by the ACNP Scientific Committee prior to submission to the Editor-in-Chief of *The Journal of Nuclear Medicine*, at which time they will undergo peer review. Accepted manuscripts resulting from this process will be published as "Presentations from the ACNP 30th Annual Meeting." ***The Journal of Nuclear Medicine Instructions for Authors*** can be accessed online at:
<http://jnm.snmjournals.org/misc/ifora.shtml>.

ACNP Honors 2004 Fellows

The American College of Nuclear Physicians (ACNP) honored 10 members with Fellow status at a gala ceremony during the ACNP's 30th Annual Meeting in January at Marco Island, FL.

Each year, ACNP recognizes as Fellows a number of outstanding physicians and scientists who have significantly contributed to the field of nuclear medicine and to the ACNP. Fellowship Committee Chairman Gary Dillehay, MD, announced the selection of the following 2004 ACNP Fellows:

James Clouse, DO, Clinton, MO
Arthur Krasnow, MD, Mequon, WI
Homer Macapinlac, MD, Houston, TX
Josef Machac, MD, Haworth, NJ
David Plone, DO, Scottsdale, AZ
Henry Royal, MD, St. Louis, MO
Jack Slosky, PhD, North Billerica, MA
Richard Vitti, MD, Princeton, NJ



New ACNP Fellows, from left: Henry Royal, Richard Vitti, David Plone, Arthur Krasnow, James Clouse, Josef Machac, Homer Macapinlac, Jack Slosky.

Nuclear Medicine Profile: Steven M. Larson, MD, FACNP

It is a great honor to write about a distinguished professor, teacher, and researcher whose contributions to the field of nuclear medicine have been exemplary. Over the past two decades I have learned state-of-the-art diagnostic and therapeutic applications in nuclear oncology from Dr. Larson at several lectures at the Society of Nuclear Medicine's annual meetings.



Steven M. Larson, MD, FACNP, was born in Tacoma, WA. His undergraduate as well as medical school training was in the University of Washington, Seattle. Dr. Larson has held faculty positions in nuclear medicine at Johns Hopkins Medical Institutions, the University of Oregon, and the University of Washington. From 1983-1988, Dr. Larson was chief of the Department of Nuclear Medicine at the National Institutes of Health in Bethesda, MD. He joined the Memorial Sloan Kettering Cancer Center in New York in 1988. Presently, Dr. Larson is the professor and chief of the nuclear medicine in the department of radiology at Sloan-Kettering Cancer.

Dr. Larson is a brilliant physician whose expertise and knowledge in the field of nuclear oncology has resulted in approval of several investigational drugs. His department is arguably the best nuclear oncology center in the country. The team of physicians and scientists who work with him have pioneered in basic science research and clinical research projects, such as radionuclide therapies, radioimmunotherapy, and diagnostic PET studies of various malignancies.

Dr. Larson is the winner of many awards including the Barson Yalow Award and the Wagner Lecture award. He is the author of 485 papers, over 200 abstracts, and books on radioimmunoassay and clinical PET in oncology.

His wife Elaine Larson, PhD, is a registered nurse. She was the dean of the School of Nursing at Georgetown University and is now a distinguished professor at Columbia University. Dr. Larson has an additional area of expertise—he plays the trumpet and guitar and he sings. Musical talent run in the family. His son, Nathan Larson, is a well-known musician. He has written several albums and composed the scores for movies including “Dirty Pretty Things” and the academy award winning “Boys Don’t Cry.” Nathan’s wife Nina is a vocalist. Dr. Larson’s daughter, Justine Larson, MD, is a resident in psychiatry at the Harvard Medical School with a special interest in child psychiatry.

Nuclear medicine science will continuously grow as long as dedicated and brilliant physicians like Steven Larson are in the field.

Simin Dadparvar, MD, FACNP

Final Letter to NRC on Medical Use of Byproduct Material Rule

February 23, 2004

Secretary, U.S. Nuclear Regulatory Commission
ATTN: Rulemakings and Adjudications Staff
Washington, DC 20555-0001

Re: RIN 3150-AH19

The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) are pleased to submit the following comments related to the U.S. Nuclear Regulatory

Commission's (NRC) proposed rule on *Medical Use of Byproduct Material – Recognition of Specialty Boards* issued December 9, 2003 (68 FR 68549).

Together, SNM and ACNP represent more than 15,000 physicians, pharmacists, physicists, scientists and technologists practicing in the field of nuclear medicine who may be affected by the revised regulation. These specialists make up the expert medical team that uses radioisotopes and radiopharmaceuticals to diagnose and treat patients with cancer, heart disease and other ailments.

Although SNM and ACNP are supportive of the revised regulation, we have several concerns about the proposed changes and implementation of this regulation. We continue to have serious concerns as to whether this regulation is truly risk informed and performance based. For example, the proposed regulation requires completion of a nuclear medicine training program which includes 700 hours of training and experience to use unsealed sources for imaging and localization studies (Sec. 35.290(a)) and, for American Board of Nuclear Medicine (ABNM) certification in Sec. 35.390, passing an examination but only requires 80 hours of training for the use of only I-131 by physicians who are not otherwise trained in nuclear medicine, radiology or radiation oncology (Sec. 35.394) with no examination. It is inconsistent to have minimal alternate training pathways while placing much more prescriptive training requirements on specialty boards that already require far more than the alternative pathway.

We suggest that the Commission reconsider formalizing in the Part 35 regulations the inconsistencies in the proposed regulations, as they would apply to any specialty board. The Commission should consider the totality of all work experience possessed by individuals who have completed an American Board of Medical Specialties (ABMS) accredited program in nuclear medicine, radiology or radiation oncology. The rule should recognize that ABMS certified nuclear medicine physicians, radiologists and radiation oncologists have unique training, experience and examinations that go well beyond the minimum requirements of the alternate pathway. The NRC therefore should require in 10 CFR 35.390 that any ABMS medical specialty board only needs to meet the same minimal requirements specified for the alternate pathway in proposed 10 CFR 35.390 (b) (1) (ii). In addition, to further remove the proposed inconsistencies, the NRC should eliminate from the regulations any additional requirements for an ABMS board such as an examination and approve ABMS boards based upon their formal training and examination procedures which will be outlined by the boards in their applications for approval.

The following responses are specific to the three questions raised by the NRC in the proposed rule.

Question 1: “Do the proposed revisions to requirements for training and experience provide reasonable assurance that Radiation Safety Officers, Authorized Medical Physicists, Authorized Nuclear Physicists, and Authorized Users will have adequate training in radiation safety?”

It is not the regulations per se that provide reasonable assurance that the Radiation Safety Officers (RSOs), Authorized Medical Physicists (AMPs), and Authorized Users (AUs) will have adequate training in radiation safety but rather the rigorous educational programs these individuals complete prior to working as an RSO, AMP or AU. For SNM and ACNP members that serve as AUs, the radiology and nuclear medicine residency programs and fellowships that our members complete include at least 4 months of training in radiation safety and protection as they apply to ensuring adequate protection of the patient and the public from radioactive materials used in nuclear medicine. In addition, as part of the American Board of Nuclear Medicine (ABNM) certification process, all AUs first take an examination that includes

questions on radiation protection and safety. These individuals also receive sufficient training in radiation safety and protection to allow them to serve as RSOs.

SNM and ACNP pharmacists, physicists and scientists who serve as radiopharmacists and AMPs complete rigorous training in their respective fields prior to taking examinations offered by their certifying boards. The boards also include questions on radiation safety and protection.

Question 2: “Should Agreement States establish the requirements to conform with this proposed rule by October 24, 2005, or should they follow the normal process and be given a full 3 years to develop a compatible rule? (See discussion under the topic “Timing of Agreement State Implementation,” above. (68 FR 68554).”

Although SNM and ACNP would prefer that the rule be finalized and effective as quickly as possible, we recognize the impact and limitation for adopting comparable regulations by the Agreement States. The Agreement States should be urged to adopt comparable regulations as soon as practical given the state legislative and regulatory processes. However, we would not contest a full 3 years for adoption being granted providing that the compatibility level for these regulations remains at Compatibility B.

Question 3: Should the word “attestation” be used in place of the word “certification” in the preceptor statements? (See discussion under the topic “Recommendations of the ACMUI,” above. (68 FR 68554).

SNM and ACNP believe it is absolutely critical to change the word “certification” to “attestation” in all of the preceptor paragraphs. In fact, we believe that the following should be inserted in place of the first sentence of all preceptor paragraphs in the December 9, 2003 draft:

Has obtained written attestation that the individual has satisfactorily completed the required training in paragraph (a)(1) or (b)(1) of this section and has achieved a level of knowledge and demonstrated the ability to safely handle radioisotopes to ensure adequate protection of public health and safety. The written attestation must be signed by a preceptor ...

We have also deleted “competency” from the preceptor statement, as we believe that the statement, “... has achieved a level of knowledge and demonstrated the ability...” is a demonstration of competency.

To be consistent, the definition of “preceptor” in Sec. 35.2 should be amended to read as follows:

Preceptor means an individual who provides or directs training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

The following provide specific comments on other sections of the proposed regulation.

Preceptor Paragraphs

In the Statement of Considerations for the proposed rule, NRC stated that the requirement for a preceptor statement would be “removed from the requirements for recognition of specialty boards.” However, it appears the NRC in drafting the rule made a grammatical mistake in the language related to the preceptor paragraphs. For example, if you look at the wording of 10 CFR § 35.390 paragraph (c) it states:

“Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (a) or (b) (1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Sec. 35.300. The written

certification must be signed by a preceptor authorized user who meets the requirements in Sec. 35.390(a), Sec. 35.390 (b), or, before October 24, 2004, Sec. 35.390, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in Sec. 35.390(b), or, before October 24, 2004, Sec. 35.930(b), must have experience in administering dosages in the same dosage category or categories (i.e., Sec. 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status.”

By requesting that the preceptor certify that the individual meets all of the requirements in **paragraph a, and not just (a) (1)** you are assuming that this individual has knowledge of the individual passing their certification exam. This may or may not be true. In fact, many preceptor statements may be signed prior to an individual sitting for their final boards. This appears to continue an unintended link between the board process and the individual signing a preceptor statement. SNM and ACNP request that all preceptor statements be corrected to refer back only to paragraph (a)(1) as appropriate in each of the preceptor paragraphs. The language in Sec.35.290 should be used as the model when making these corrections. Clarification needs to be provided in the Statements of Consideration that individuals may submit more than one preceptor statement, as applicable, for all categories of AU, AMP, or RSO.

10 CFR § 35.50 *Training for Radiation Safety Officer (RSO)*

We commend NRC for the additional paragraph in 10 CFR § 35.50 which recognizes that medical physicists who do not qualify as AMPs may also serve as RSOs. This is an important addition since AMP only applies to medical physicists practicing in therapeutic programs. However, the phrase “*under § 35.51 (a)*” should be deleted from § 35.50 (d) (2) (i) because including the tie will limit RSO medical physicists to medical physicists practicing in therapy. It is absolutely critical that qualified medical physicists other than AMPs be able to serve as RSOs. Medical physicists, who are certified in diagnostic radiology or nuclear medicine, need to continue to be able to serve as RSOs.

10 CFR § 35.390 *Training for use of unsealed byproduct material for which a written directive is required.*

As 10 CFR § 35.390 applies to nuclear medicine physicians Section 35.390 (a) (1) states:

“(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in paragraph (b)(1) of this section.”

As indicated above, the SNM and ACNP believe that the NRC should not specify in Part 35, training requirements for ABMS boards that exceed the minimum requirements of the alternate pathway. If the NRC insists on maintaining the current language in the training requirements we suggest the following change to 10 CFR § 35.390 (a) (1):

(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy training program, or a nuclear medicine training program, or a program in a related medical specialty that includes 700 hours of training and experience as described in paragraph (b)(1) of this section.

Currently nuclear medicine residency programs are 2 years in duration. The offered change removes the confusion of whether the 3 years of residency applies to radiation therapy training programs as well as nuclear medicine training programs. The language in the proposed rule is a change from the existing 10 CFR § 35.390 and was suggested by the Advisory Committee on

the Medical Uses of Isotopes (ACMUI) to reflect the recognition of radiation therapy residency programs in 10 CFR § 35.390. Apparently the need for the added punctuation and language we are suggesting was overlooked.

10 CFR § 35.390(G)(3) and (4) “parenteral administration”

Sec. 35.390 (G) deals with the therapeutic administration of certain unsealed source radionuclides orally and by parenteral administration, i.e. “by way of the intestines.” As radiopharmaceutical therapies are now delivered by a variety of routes, we believe that “Parenteral administration” should be changed to “Administration by any route” to make the section all encompassing.

We commend the NRC’s commitment to developing regulations through an interactive process with the medical community and we look forward to working with the Commissioners and staff to implement this rule in a timely fashion.

If you have any questions regarding our concerns on implementation of this rule, please let us know. Representatives of SNM and ACNP would be pleased to meet with you at your convenience to discuss this regulation. You may contact Bill Uffelman at 703-708-9773 or by email at wuffelman@snm.org to arrange a meeting or conference call.

Sincerely,

Dr. Henry D. Royal
President
Society of Nuclear Medicine

Dr. Warren H. Moore
President
American College of Nuclear Physicians

ACNP’s Strategic Planning Meeting

The ACNP Leadership Council convened for a highly productive strategic planning session on January 12th, at this year’s Annual Meeting. The purpose of the meeting was to identify clear objectives for the organization over the next three years and to put solid strategic direction in place. Those in attendance included the president and president-elect as well as nine past presidents who participated in this meeting. Six past president’s recommendations were included in the discussion. The ACNP staff was represented by Virginia Pappas, Gregg Robinson and William Uffelman. ACNP invited Sue Wallace, PhD, to serve as facilitator for the strategic planning meeting.

The following goal statements resulted from the meeting:

Key goals for the next 12 months:

- Increase the membership base
- Enhance income to the organization
- Expand cooperation with other organizations

Current thinking is that this platform of building membership and financial strength will facilitate the following 2year goals for the organization:

- Increase resident involvement
- Provide outreach resources to local referring physicians
- Provide expertise for reimbursement issues

A great deal of work that went into defining specific actions that would help to achieve these goals. The Board of Regents wanted to ensure that a goal not be defined without tangible action identified to achieve it. Just a few of the many examples of specific actions under consideration are: establish and activate a resident organization, develop a “road show” focused on practical

enhancements to NM practice and billing, work with industry to assure that low-profit-margin radiopharmaceuticals do not get eliminated, provide reimbursement training, develop a PET mentor program, and promote quality practice standards. Task force leaders will be assigned for the major areas. By the end of March it is anticipated that complete action plans and timelines will be defined, and task force activity will be in full swing. Watch future newsletters for updates.

Sue Wallace, PhD

Letter to ABNM

January 12, 2004

Lawrence E. Holder, MD, Chair
American Board of Nuclear Medicine

Dear Dr. Holder:

I am writing this letter to be shared at the American Board of Nuclear Medicine Annual meeting in the Bahamas. During the ACNP Board of Regents meeting on January 11, 2004, as well as in earlier discussions with members of the ACNP the following items were addressed:

1. The ACNP supports the extension of the nuclear medicine residency training programs to three years in view of new applications in our field including the radionuclide therapies and PET imaging.
2. The ACNP discourages a shorter training period i.e. 1 year for training the radiology fellows. Shorter training will result in inadequate exposure of the fellows to all aspects of nuclear medicine and further will take away job opportunities for future nuclear medicine physicians.
3. The questions written by the nuclear medicine physician for ABR certifications are too simplified. This has resulted in inadequate preparation of the radiology resident for the nuclear medicine portion of the ABR exam. The radiology trainees only study the requisites and believe that the nuclear medicine portion of the board requires limited preparation.
4. More than any other time in the history of nuclear medicine, we are facing a shortage of manpower, presenting a great opportunity to train qualified people. ABNM, SNM and ACNP should consider working together to start the strategic planning for the immediate and long-term future of the specialty.
5. The training and certification of the residents in CT/MRI is extremely vital and the Board is encouraged to give immediate consideration to incorporate it in the curriculum.
6. The practicing nuclear medicine physician needs to receive appropriate credentialing to interpret PET/CT studies. ABNM can set the standards, and in conjunction with SNM and ACNP the credentialing programs could start in the near future.
7. ACNP will assure that programs for evaluation and credentialing for nuclear medicine physicians that do PET/CT will be developed and implemented as soon as possible.

ACNP would like to thank the ABNM and residency program directors for considering our recommendations. If you have any questions or comments, I can be reached at (215) 662-3021 or

you can contact Warren Moore, MD, the new ACNP President at (832) 355-3126. Your favorable response is very much appreciated.

Sincerely,

Simin Dadparvar, MD
President
American College of Nuclear Physicians

Residents' Organization

Welcome residency/fellowship trainees!

Many thanks to the residents/fellows who elected me as the first president of the ACNP Residents Organization at last month's 30th Annual Meeting of the ACNP in Marco Island, Florida. Upon the completion of residency/fellowship training, many of us suddenly realized the importance of the non-clinical aspects of our specialty. Each of the three organizations in the nuclear medicine specialty—the American College of Nuclear Medicine (ACNM), the Society of Nuclear Medicine (SNM), and the American College of Nuclear Physicians (ACNP)—can play an important role in the young physician's new role as an actual practitioner of nuclear medicine. While ACNM and SNM focus largely upon education, the ACNP is unique in that we focus on two priorities—government relations and professional development.

In the next *Scanner*, I will introduce the topic of government relations—what it is, why it is relevant at the residency/fellowship level, and how we can learn more about it. Future issues will cover professional development, and will discuss the launch of a nationwide mentorship program between attendings and residents/fellows. There will also be information regarding salary surveys and the job market. The ACNP website already has a useful "Professional Enhancement" section for residents/fellows. Please see the new resident's section on the website.

The ACNP Residents Organization welcomes your participation, input, and contributions. My email address is henrykimmd@yahoo.com. Administratively, we have openings for a vice president and treasurer. Meanwhile, please sign up as ACNP members and help spread the word about the free ACNP membership for residents/fellows, made possible by the generous support of Bristol Myers Squibb, who is subsidizing the otherwise \$50 annual membership fee. The simplified half-page version of the membership application is available as the last page of the June 2003 issue of the *Scanner* newsletter. Download this from the *Scanner* archive section of the ACNP website <http://www.acnponline.org/>

Lastly, please help spread the word among nuclear medicine trainees about the upcoming American Association for Cancer Research/American Society of Clinical Oncology (AACR/ASCO) workshop entitled, "Methods in Clinical Cancer Research." Scheduled for July 31-August 6, 2004 at Vail, CO, the event is being advertised as "an educational workshop in the essentials of effective clinical trial design for clinical fellows and junior faculty clinical researchers." Please note that the online application is due Monday, March 15, 2004, and involves the submission of a list of publications, an essay, a recommendation letter, and a one pager of the clinical trial protocol you will write at the actual workshop. The URL is <http://www.aacr.org/4300m.asp>.

*Henry Kim, MD
President
ACNP Residents Organization*

FDA Sees Rebound in Approval of Innovative Drugs in 2003

The Food and Drug Administration announced in January improved results over last year on overall drugs and biologics approvals for calendar year 2003, and decreases in the time it took the Agency to review and approve most applications.

A highlight of this success was the approval of 21 New Molecular Entities (NMEs) with active ingredients never before marketed in the United States. This number of NME approvals is up from the calendar year 2002 total of 17. Priority approvals, approvals for priority products of special medical importance, increased from 2002 as well: There were 14 priority NDAs and 9 priority NMEs, compared to 11 and 7 in 2002, respectively.

The Agency's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) approved 466 new and generic drugs and biological products, many of which represent significant therapeutic advances. In particular, the Agency saw a significant increase in the number of approvals on NMEs, which typically represent the most novel new drugs.

"FDA is making new treatments available more quickly," said HHS Secretary Tommy G. Thompson, "And I expect FDA's new innovation initiatives announced in early 2003 will lead to even faster approvals of safe and affordable medical treatments in the coming years."

Through a series of special new initiatives now being implemented, plus a continued dedication to timely and complete reviews of every application, FDA is committing to reach a goal of reducing the average total FDA time for review before marketing approval by 30 days for priority applications and two months for standard applications for the first half of the approval cohort for applications submitted in FY 2005-07 and beyond. This correlates to a 10% reduction or better.

The FDA already works hard to keep review times short, as prescribed under PDUFA. Under new initiatives the Agency is undertaking, FDA will be working to decrease the number of applications requiring multiple review cycles. The improvements in application quality needed to reduce the number of review cycles will be addressed through initiatives to improve the quality and frequency of FDA-industry interactions during drug development and during the first cycle of review. If sponsors take advantage of these programs and fulfill their obligation to file better applications, the result will be not just shorter time to approval, but a more efficient use of both company and agency resources.

Encouraging Innovation in Drug Development for the Coming Years

In 2003, the Food and Drug Administration announced several new initiatives to help encourage innovation in medical product development and speed access for all Americans to safe and affordable new medicines. The Agency anticipates that these initiatives will help build on this year's encouraging results and allow FDA to meet its ambitious goals for faster therapeutic development.

Accelerating development of new medical products

In January 2003, FDA launched a broad new agency-wide initiative to speed development of innovative medical technologies. FDA is committed to reducing total review time for new drugs and biologics across the board by approximately 10.5% through this initiative. Such reductions in review time for drugs and biologics, as well as for new devices, will place much needed treatments in the hands of patients faster, thus help treat and prevent diseases and improve overall health.

The first element of this innovation initiative involves a reduction of multiple cycle reviews. FDA is undertaking a root cause analysis for product approvals that require more than one review cycle and many months of additional development time. Based on the results of this assessment, the Agency will take actions to prevent avoidable cycling. New pilot programs are also underway which include earlier communication with product manufacturers. Evidence shows that upfront, focused communication with product developers about FDA standards can often help the developers get the application right the first time around.

The second element of the innovation initiative involves the implementation of a “quality systems” approach to medical product reviews. Best management practices are being identified and implemented internally for FDA’s scientific review processes. Additionally, new peer review programs, coupled with more empirical data, will allow drug and other scientific reviewers to exchange ideas and use each others’ experience to learn about best practices.

Third, FDA is working collaboratively with the National Cancer Institute and other government agencies, academic researchers, health care providers and patients to address key clinical and scientific issues and to clarify regulatory pathways for targeted disease areas and new technologies. Through joint workshops and conferences, FDA is working to provide clarity to product innovators in these critical medical areas, thereby improving the efficiency and anticipated quality of submitted applications. FDA has issued specific new guidances on these issues including guidance on investigational new drug (IND) exemptions for studies of lawfully marketed cancer drug or biological products; guidance on integrating pharmacogenomic testing into the drug development processes; and draft guidance for reviewers of human somatic cell therapy INDs. FDA and NCI also announced a new system for receiving INDs electronically to help foster better and faster innovation in oncology.

ACNP 2004 “Man of the Year”—Jack Slosky

Accomplished, dedicated, respected—all words that epitomize this year’s ACNP “Man of the Year,” Jack Slosky, PhD, MBA, FACNP.

A unanimous selection by the ACNP’s Board of Regents, Jack received the 2004 “Man of the Year Award” at the recent 30th anniversary ACNP annual meeting in Marco Island, Florida. In addition, Jack was also named an ACNP Fellow—an honor bestowed upon only a select number of ACNP members.

“The ‘Man of the Year’ award came as a total surprise to me,” said Slosky. “I have been lucky enough to be surrounded with tremendous colleagues throughout my career, and they share much of the credit for these honors. I am truly humbled to have received this award.”

Jack Slosky accepts Fellowship award from ACNP president Simin Dadparvar.



An Impressive Career

A nuclear medicine industry stalwart, Jack has been involved in the field for the better part of 30 years, the last 25 in various research and managerial roles at Bristol-Myers Squibb Medical Imaging headquartered in Billerica, Mass.

Born and raised in Warsaw, Poland, Jack earned his master’s degrees in Mathematics and Biochemistry and

his doctorate degree in Biochemistry/Radiochemistry from Warsaw University. Jack later earned a Certificate of Special Studies in Administration and Management from Harvard University and an MBA in High Technology from Northeastern University.

Jack began his professional career in 1973, when he came to America to pursue a postdoctoral assignment in academic research that took him throughout the US and Brazil. During this period he co-authored more than 40 scientific papers for a variety of international chemical and pharmacochemical journals.

“Coming to the U.S. had been a dream of mine for a long time,” said Jack. “The ability to go into a library and read any book you wanted without fear was such a refreshing change from the persecution and censorship of communist Poland. While it was difficult in a sense to leave my homeland, America provided me with a vast range of opportunities that simply didn’t exist in communist Poland.”

In 1979, Jack joined the Research and Development department at Bristol-Myers Squibb Medical Imaging (then the New England Nuclear Corp.) overseeing the process chemistry area. During the mid-1980’s, Jack led the team that developed the raw materials, process chemistry and formulary for Cardiolite[®] (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection). In fact, Jack holds two patents supporting the chemistry of Cardiolite.

After several years in Research and Development, Jack transitioned into marketing where he held several managerial positions integral to the successful launch of Cardiolite in Europe, Canada, and the U.S. Jack then moved into his current leadership role in Health Economics Policy and Professional Relations. In this role, Jack maintains a high level of visibility within both the industry and government arenas, championing healthcare economics and reimbursement issues in support of patients and the entire medical imaging community.

Tireless Advocate for Nuclear Medicine

In addition to his efforts on behalf of ACNP to educate young physicians about the nuclear medicine industry and its related socioeconomic issues, Jack lends his vast experience and expertise in the industry to a number of important trade groups.

Most notably, Jack is the current chairman of the Nuclear Medicine Industry Association of North America (NMIA-NA), and co-chairs the Health Care Committee for the Council on Radionuclides and Radiopharmaceuticals (CORAR). In these positions, Jack continues his tireless efforts on a variety of issues affecting patients and the nuclear medicine community.

Tree Farmer and Devoted Family Man

Given his career at Bristol-Myers Squibb Medical Imaging and all of the work that Jack does on behalf of the nuclear medicine industry, it may be hard to believe that he has time for other interests. Rest assured, outside of the nuclear medicine community Jack’s hobbies are, to say the very least, diverse. A certified tree farmer, Jack and his wife, Ursula, spend a great deal of time tending to land in New Hampshire that they purchased 20 years ago and have transformed into a tree farm that Jack lovingly refers to as “their little forest.”

When not tending to his trees, Jack keeps busy pursuing another one of his many hobbies—movie collecting. According to Jack, he has a “significant” movie collection from around the world. Included in his collection are all of the films that have received the Academy Award for “Best Picture.” Jack’s collection also includes nearly all of the films that have received the “Best Foreign Language Film ” award.

Jack's greatest enjoyment and satisfaction comes from his family. A devoted family man, Jack is most proud of not his own accomplishments, but rather those of his wife and their two children—Cypriana and Justin.

Ursula holds a PhD in Medicinal Biochemistry from Warsaw Medical School and is a widely respected clinical researcher in her own right. Born and raised in Poland and fluent in several languages, she is currently working as a medical and legal interpreter.

Cypriana greatly enjoys her work as a teacher. She has an undergraduate degree in music and French and a master's degree in early childhood development from Tufts University. An accomplished singer, Cypriana regularly performs as a member of the Tanglewood Festival Chorus with the world-renowned Boston Symphony Orchestra and the Boston Pops.

Justin, who inherited his father's love of film, recently graduated from Brown University and is now living in California, where he is pursuing a screenwriting career.

"While the awards I have received over the years are all tremendous honors, I am also very proud of my family's accomplishments and the joy that each of them has brought to my life," Slosky commented.

*Kevin Nash
Bristol-Myers Squibb Medical Imaging*

News Scan from www.acnponline.org

Mark McClellan Nominated to Head CMS

Posted February 23, 2004

Tommy G. Thompson, secretary of Health and Human Services, announced on February 20 that President George W. Bush has nominated Mark McClellan, MD, PhD, to be administrator for the Centers for Medicare & Medicaid Services (CMS). McClellan will replace Thomas Scully who resigned as CMS administrator in December. McClellan will continue to serve in his current post as commissioner of the Food and Drug Administration until his appointment to the CMS is confirmed by the Senate.

"Mark McClellan will be an outstanding leader for the Centers for Medicare & Medicaid Services as the agency works to implement the new Medicare law and increase access to quality health care for American families," said Thompson. "At the FDA and throughout his career, Dr. McClellan has served the nation admirably while demonstrating exemplary leadership that will continue our efforts to build a strong and responsive CMS. His comprehensive understanding of the American health care system and dedication to public service make Dr. McClellan an ideal choice to lead CMS at this important time."

Gregory B. Jaczko Nominated for NRC

Posted February 17, 2004

President George W. Bush announced on February 12 his intention to nominate physicist Gregory B. Jaczko, PhD, to be a member of the Nuclear Regulatory Commission (NRC), for the remainder of a five-year term expiring June 30, 2008.

Mr. Jaczko currently serves as appropriations director for Senator Harry Reid (D-NV) and teaches a science and policy course at Georgetown University. Sen. Reid is strongly opposed to the NRC's plan to store nuclear waste at Yucca Mountain in Nevada.

Jaczko previously served as Sen. Reid's science policy advisor. Prior to this position, Mr. Jaczko worked for the U.S. Committee on Environment and Public Works. He earned his bachelor's degree from Cornell University and a PhD in physics from the University of Wisconsin-Madison.

Two New Cosponsors for RadCARE in Senate; Three for CARE in House Posted February 11, 2004

Two more senators and three representatives have signed on as cosponsors of the CARE Act. Senator Tim Johnson (D-SD) and Senator Richard Durbin (D-IL) signed on to S 1197, the RadCARE bill, the Senate version of the Consumer's Assurance of Radiologic Excellence (CARE) act. Three more representatives have cosponsored the house version, HR, 1214, the CARE Act. They are Rep. Maurice Hinchey (D-NY-22), Rep. Mike Rogers (R-MI-8), and Rep. Steve Rothman (D-NJ-9). This brings the total Senate cosponsors to 9 and the total cosponsors of the House bill to 61.

NRC Revises Safety Standards for Packaging and Transportation Of Radioactive Material

Posted January 28, 2004

The Nuclear Regulatory Commission (NRC) has issued a final rule revising safety standards for the packaging and transportation of radioactive material. Most of the changes update U.S. regulations to make them similar to international standards established by the International Atomic Energy Agency (IAEA). (See the Related Items box below for a link to the final rule.)

The NRC's current transportation regulations are based, in part, on those developed by the IAEA, a worldwide standard-setting organization. The IAEA periodically revises its transportation standards to reflect scientific and technical advances, and the NRC accordingly updates its own regulations to be compatible with those of the IAEA. The current revision is being coordinated with the Department of Transportation, which is the lead federal agency for transportation regulations in the United States.

Among other things, the final rule would phase out the use of older approved designs for certain transportation packages. This change is being imposed, despite an excellent safety record for the older package designs, in order to bring U.S. transportation regulations into alignment with those in place internationally and to take advantage of safety enhancements in newer designs. Industry will have four years to phase in the use of newer designs.

The final rule also grants a petition for rulemaking to eliminate double-seal requirements for plutonium shipments. There is no comparable IAEA requirement for the use of double seals on packages containing plutonium, and current single-seal packages used for transporting spent fuel would provide adequate accident protection when applied to packages transporting plutonium. The final rule maintains a requirement, however, that shipments of greater than 20 Curies of plutonium must be made with the contents in solid form.

A proposed rule, published in April 2002, sought public comment on 19 open issues, 11 of which were designed for consistency with the IAEA standards. A total of 190 comments were received. The final rule defers a decision on a proposal to allow NRC certificate holders to make limited changes to dual-purpose spent fuel storage and transportation packages and makes other minor changes to the proposed rule. Public comments and NRC responses are discussed in the *Federal Register* notice on the final rule, published January 26, 2004.

The final rule will be effective October 1, 2004.