



Court Rules in Favor of FDA in Syncor Case

Judge Emmet G. Sullivan, U.S. District Court Judge issued his decision on the Syncor International et al. versus Donna E. Shalala et al. case on October 18, 1996. This case, in which the Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) participated, questioned the appropriateness of the FDA's applicability of regulations applying to PET radiopharmaceuticals. Syncor et. al (represented by Alvin J. Lorman of Mintz, Levin, Cohn) made the following arguments which the judge ruled on.

The court resolved five issues raised in the suit including: (a) whether plaintiffs challenge to the FDA's February 27, 1995 determination that PET radiotracers require FDA-approved New Drug Applications (NDAs) is ripe for the court's review; (b) whether the FDA's regulation of PET drugs, as published in the Federal Register of February 27, 1995, violates the Administrative Procedure Act; (c) whether the FDA, in regulating PET drugs, exceeded its statutory authority under the Food, Drug and Cosmetic Act (FDCA) by allegedly regulating intrastate, as opposed to interstate commerce; (d) whether, by regulating pharmacies, the FDA has violated the Tenth Amendment to the U.S. Constitution, and (e) whether the FDA's February 27, 1995 Federal Register Notice was an arbitrary and capricious denial of Syncor's May 1992 citizen petition.

The judge ruled in favor of Syncor regarding the ripeness issue,

but ruled in favor of the FDA regarding the other four issues.

NRC Strategic Assessment Hearing

Dr. Darrell McIndoe, on behalf of the SNM and ACNP, presented testimony regarding the regulation of the medical program at a Nuclear Regulatory Commission (NRC) hearing on October 24, 1996. During a series of discussions at the hearing on October 24, 1996, the NRC requested testimony on options for regulating the medical program as outlined in its strategic assessment document. Representing the views of the SNM and ACNP, Dr. McIndoe outlined the following points in his testimony:

1. NRC should classify diagnostic nuclear medicine as low risk and exempt it from all but general licensing provisions.
2. NRC should hold an enhanced participatory workshop to determine the best way to approach regulation of therapeutic nuclear medicine, focusing on performance-based regulations.
3. NRC should classify nuclear pharmacies together with nuclear medicine procedures, and not in the same class of licensees as manufacturers.

Several states and the Council on Radionuclides and Radiopharmaceuticals also presented similar testimony at the hearing.

—David Nichols is the associate director of the ACNP/SNM government relations office

News Briefs

First Nuclear Medicine Board Equivalent Examination in Hong Kong



From left to right: Choi Pat Tat, Wong Ka Nin, Henry N. Wagner, King Sun and Wong Kwang Kuen.

Several months ago, nuclear medicine academic leaders from Hong Kong and two Society of Nuclear Medicine members met to create the first annual nuclear medicine board equivalent examination ever held in Hong Kong.

participated in the oral examination. The exam, given in English, included three parts: written, image interpretation and oral. Four of the six candidates passed. They were: Choi Pat Tat, Wong Ka Nin, Chu King Sun and Wong Kwang Kuen.

On October 21, 1996, six candidates were examined for certification as specialists in nuclear medicine in Hong Kong. Michael N. Maisey, MD, of Guy's and St. Thomas in London and Henry N. Wagner, Jr., MD, of John's Hopkins Medical Institutions in Maryland helped make up the written examination and

Wagner, as one of the founders of the American Board of Nuclear Medicine in 1971 and still active in the nuclear medicine field, said he was honored to participate in the creation of this exam. "This [exam] is a step forward in nuclear medicine becoming a recognized independent specialty around the world," Wagner said.

SNM Online

When's the next SNM chapter meeting? Visit the SNM home page on the Internet for quick answers to these questions and more. Which staff member should be contacted about membership? What publications, products and services are available? The SNM home page is also a great source of basic educational information on nuclear medicine, such as the terminology and history of nuclear medicine. The page's *Newsbriefs* section will

give you up-to-the-minute information. If you have a news item of interest to the nuclear medicine community, please send a brief, 100 words or less, announcement to John Childs, Director of Communication Services, SNM headquarters office at jchilds@snm.org. You can log onto the home page via the World Wide Web at <http://www.snm.org>. ■

ADAC Wins Malcolm Baldrige Quality Award

In October, President Clinton and Commerce Secretary Mickey Kantor announced ADAC Laboratories, head-

quartered in Milpitas, CA, as one of four 1996 winners of the Malcolm Baldrige National Quality Award. ADAC is the first health care manufacturer to be honored by this award that recognizes achievements in quality and business performance. The company received the award in the manufacturing category. The other two award categories are service and small business.

The Baldrige Award is granted by the U.S. Department of Commerce and was initiated by Congress to promote quality awareness, recognize quality achievements and publicize successful quality strategies of U.S. companies. Since its establishment in 1987, 28 companies, including the four 1996 recipients, have received the honor. Former winners include Cadillac

and AT&T. A team of examiners evaluates each applicant company on leadership, information and analysis, strategic planning, human resources development and management, process management, business results, and customer focus and satisfaction.

"The adoption of the Malcolm Baldrige criteria, based on continuous improvement and intense focus on customer satisfaction, has been a key factor in our success over the past four years," said David Lowe, ADAC's chairman and chief executive officer. ADAC is a world market leader in nuclear medicine and a leading supplier of radiology and laboratory information systems in North America. ■



ANNOUNCING

The American Board of Science in Nuclear Medicine 1997 Certification Examination

The 1997 examination will be given Sunday, June 1, 1997 in San Antonio, Texas in conjunction with the 44th Annual Meeting of the Society of Nuclear Medicine.

The examination is written and consists of two parts —

Part One (3.5 hours) assesses knowledge of basic aspects of Nuclear Medicine Science.

Part Two (2.5 hours) examines in depth the knowledge of a predetermined subspecialty area of the candidate's choice including:

- Nuclear Medicine Physics and Instrumentation
- Nuclear Pharmaceutical Science and Radiochemistry
- Radiation Protection

Completed Applications must be postmarked by March 14, 1997. The examination fee is \$450 (\$400 refundable if you do not qualify).

For applications and more information, please contact:

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