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SECTION ON NUCLEAR PHARMACY
ACADEMY OF PHARMACY PRACTICE
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Presented by Kenneth Breslow, Chairman
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It was a year ago when then chairman Ronald Callahan described his activities by paraphrasing a definition of sailing as "being hours and hours of quiet pleasure interrupted by moments of sheer panic". His term was fraught with an over abundance of crises relating to regulatory agencies and other professional organizations. It is to Dr. Callahan's credit that when control of the ship was turned over to me, we were on a straight course and the water had but a ripple on its surface.

This past year has been relatively calm with no urgent crises. The regulatory waters were moderate, but there were no breakers to cause distress. Much of the calm in the area of regulatory affairs may be due to the philosophy of the Reagan administration, which has effectively reduced the promulgation of new regulations and guidelines. There have been, however, certain regulatory activities which the Section has closely monitored through the efforts of Lynn R. Hendershott and the Regulatory Affairs Committee.

In March 1980, a draft guideline entitled Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment was widely circulated and published in the Federal Register of April 11, 1980 (45 FR 24920). The purpose of this guideline is to assist nuclear pharmacies in determining if they are required to register as a drug manufacturer. The Section responded formally to this proposal last year. At this time, the summary of solicited comments with FDA response along with the final guideline has not yet been published in the Federal Register. In a recent
conversation with the Section liaison to the FDA, Mr. Jerome Halperin, Deputy Director of the Bureau of Drugs, it was indicated to me that there is no strong urgency for the final guideline to be published and that one should not expect to see it in the very near future. I have been able to obtain an advance copy of the final proposed guideline along with FDA's answers to comments. In reviewing this document, I feel that in general, the profession has received very fair and reasonable treatment by the FDA in this matter. The guideline is essentially unchanged from the March 1980 draft.

Last year, the Section also responded to a proposed NRC guideline on the licensing of nuclear pharmacies. In a recent communication with Pat Vacca of the NRC, it was indicated that no immediate action will occur in regards to publishing a final guideline.

In the January 23, 1981 Federal Register, the Environmental Protection Agency published a proposed guideline entitled Federal Radiation Protection Guidance for Occupational Exposures. This proposal in general would recommend more stringent and burdensome regulations regarding radiation protection of workers. Late last year, it was learned that the EPA is considering one of three options regarding this proposal: 1) not to make any changes in existing regulations; 2) to adopt the proposal with fine tuning and minor changes; and 3) to change direction entirely and adopt the International Commission on Radiation Protection publication #26, which is a separate and distinct worker safety standard. To this date, no action has been taken to adopt the proposed guideline.

There were other regulatory matters during this past year that, because they were reasonable and consistent with nuclear pharmacy practice, and do not cause additional burdens on the professional community, the Regulatory Affairs Committee monitored, but did not formally respond to.
These include: 1) NRC proposed rule (Federal Register, September 1, 1981) "Measurement of the Activity of Radiopharmaceutical Doses", and 2) a Department of Transportation final rule (46 FR 5298, January 19, 1981) stating that the federal government takes precedence over local and state regulations concerning radioactive materials transportation.

During this past year, the Section has established an excellent liaison with the Society of Nuclear Medicine through Captain Bill Briner, Pharmacist, Duke University Medical Center. I would like to thank Pharmacist Briner for his cooperative efforts with the Section concerning regulatory matters. I encourage the Section to continue this strong relationship which has been developed with the Society of Nuclear Medicine. Again, I thank Lynn Hendershott and the members of his committee for their dedicated efforts in the regulatory arena.

The Educational Affairs Committee under the Chairmanship of William Baker, has completed the initial revisions of the Nuclear Pharmacy Practice Standards. All section members were sent a copy of the proposed revision and members were asked to evaluate and comment on the document. Several comments were received by the committee. The final validation and adoption procedure now needs to be defined, and I look forward to progress on this front during this week. Through close cooperative efforts with the ASHP SIG on Nuclear Pharmacy and the Educational Affairs Committee, the ASHP Accreditation Standard for Residency Training in Nuclear Pharmacy has been finalized and adopted. The Standard has been published in the American Journal of Hospital Pharmacy, Vol. 38, December, 1981. The Educational Affairs Committee was solicited for comments regarding input into educational requirements to qualify radiopharmacists as radiation safety officers for licensure by the Nuclear Regulatory Commission. It was suggested that a committee consisting of representatives from the Section on Nuclear Pharmacy,
Educational Affairs Committee, SIG Section of the American Society of Hospital Pharmacists, and the Radiopharmaceutical Science Council of the Society of Nuclear Medicine, would be a workable committee to accredit training programs. The suggestion for this committee was modeled after a committee that has been in effect in the state of Utah for evaluating continuing education programs in pharmacy. The main purpose for this committee would be to aid in the identification of radiopharmacy training programs that adequately train the pharmacist in the area of radiation safety so that licensing by the NRC would be facilitated. This idea is worthy of further exploration in the coming months. Much appreciation is expressed to Bill Baker and his committee for their conscientious efforts in the past year.

The Communications Committee, chaired by Robert Beightol, has continued its fine job of providing information on a variety of subject matters in a regular and timely fashion and in coordinating other publications. Last year, the Communications Committee worked with the Section in developing and distributing a survey of nuclear pharmacists. The preliminary results were presented at the annual meeting last year and the final results have been submitted for publication by Geoffrey Levine to Contemporary Pharmacy and is currently in press. Again, thanks go to Bob and his committee for continued service to the Section.

The Nominations Committee, chaired by past chairman Dr. Ronald Callahan, had the difficult task of selecting the candidates for Chairman-Elect. The nominees for this year are Robert Beightol, Salt Lake City, Utah and Arthur Solomon, Atlanta, Georgia.

I would like to congratulate the Program Committee and its chairman, Dr. Jack Coupal, for working very hard in efforts to create a diverse and highly informative program. We all look forward to a valuable learning
experience this week.

Dr. Stanley Shaw has served as Historian for the Section this past year. Dr. Shaw has formed an Awards Committee and will describe the objectives, criteria and mechanisms for a Founders Award during the Section's business meeting this week.

Of course, a milestone has been reached this week with the administration of the first official certification exam for Nuclear Pharmacy Practitioners. I would like to congratulate Dr. Richard Penna and all of the other people who have worked so long and hard to guide the certification process to this final achievement.

The challenge of this past year has been very rewarding to me and I am thankful for the opportunity to serve my profession. I especially wish to thank Mr. Jim Emigh and the APhA staff for their superb support and close cooperation. My personal gratitude goes to all committee chairmen who made my job more enjoyable.

Respectfully submitted,

Kenneth Breslow

Kenneth Breslow, Chairman
Section on Nuclear Pharmacy