History of Nuclear Pharmacy: A Look Back and A Glimpse Ahead

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Presentation Outline

• In the Beginning
• The Generator
• Centralized Services
• Hospital Services
• Professional Recognition
• A Glimpse Ahead

Evolution

• In the Beginning the Earth was Formed
• Naturally Occurring Radioactivity Existed
• Henri Becquerel Discovered Naturally Occurring Radioactivity
• George Hevesy Introduced the Tracer Principle
• Hermann Blumgart Performed the First Applications of Radioactive Tracers in Medical Research
• Pioneers in Nuclear Medicine Developed Instruments, Products and Clinical Applications

Rectilinear Scanner
The Radiopharmaceutical Industry 1965

- Major Suppliers
  - Abbott Laboratories
  - Squibb
  - Mallinckrodt

- Radionuclides in Common Use
  - I-131 Labeled to Various Compounds
  - Hg-203 and 197 Chloromerodin
  - Cr-51 Chromate
  - Se-75 Selenomethionine
  - Fe-59 Chromate and Citrate
  - Co-57 Cyanocobalamin
  - Sr-85 Nitrate

Early Radiopharmacy Services

- Radioisotope Laboratory in Chicago in Early 1950’s
- Captain Bill Briner at the NIH
- Established the NIH Radiopharmacy in 1958
Captain Bill Briner

- Father of Radiopharmacy
- Strong Proponent of Pharmacy Services for Radiopharmaceuticals
- Challenged Pharmacists in Publications
- Laid the Foundation for Practice Today
- Trained and Mentored Individuals Contributing to the Development of the Field
Radiopharmaceuticals Are Drugs
The Modern Hospital August, 1960
William H. Briner

"To assure oneself at the outset that certain radioactive products administered to patients are in fact pharmaceutical entities, one needs only to consult the current revision of the United States Pharmacopeia. In the fifteenth revision of this compendium, there appear several monographs outlining specifications for radiopharmaceutical products which were in sufficiently wide use to warrant inclusion in this volume at the time it became official on December 15, 1955."

"If products such as those under consideration are pharmaceutical in nature, why, then, are not more pharmacists actively engaged in the purchasing, storing, compounding, assaying and dispensing of these materials."

Radiopharmacy The Emerging Young Specialty
Drug Intelligence, January 1968
William H. Briner

"Byproduct material shall not be used in humans until its pharmaceutical quality and assay have been established."

"It is tragic indeed that most hospital pharmacists have no conception of either the meaning of the significance of this rather simple statement of concern shown by a federal regulatory agency for the safety of an ever-increasing number of patients in American hospitals."

Radiopharmacy The Emerging Young Specialty
Drug Intelligence, January 1968
William H. Briner

"Their meaning for pharmacists should be crystal clear—when the property of radioactivity is introduced into a compound by some artificial means, as in a nuclear reactor, serious consideration must be directed to the question of whether or not the resultant material is of a pharmaceutical quality compatible with its safe use in human subjects."

"The obvious question posed by this statement is, who shall assess the pharmaceutical quality of a radioactive product."

"Does it not seem reasonable, then, to suggest that pharmacists ought to be competent to make judgments concerning the pharmaceutical aspects of radiopharmaceutical products?"
Dr. John E. Christian

- School of Pharmacy at Purdue University
- Early Proponent for Pharmacy Involvement
- Stated that Hospital Pharmacists Become Involved in a 1950 Article
- Prepared First Radiopharmaceutical Monographs for the USP
- Established Courses and Program at Purdue University

Dr. John E. Christian (continued)

- Trained Individuals that contributed to the Development of Radiopharmacy and Industrial Products
Radioactive Isotopes In Hospital Pharmacy


John E. Christian

"The Hospital Pharmacist Should Be Prepared To Provide Information And Assistance And Take The Initiative In The Establishment Of Facilities And Know How For Utilization Of These Materials In Medical Practice And In Medical Research."

"In Conclusion, One Might Logically Again Ask, 'What Can The Hospital Pharmacist Contribute To The Radioisotope Program In The Hospital?' The Answer — (1) Be Authoritatively Informed On The Basic Principles, Applications, Methods Of Obtaining, Facilities Necessary, Means Of Control, And Sources Of Information Of Radioactive Isotopes Used In Medical Practice (2) Encourage The Hospital Administration To Look Into The Possibilities Of Establishing Necessary Facilities For Isotope Utilization. (3) Take Active Interest In And/Or Assist In The Radioisotope Program Of The Institution."

Applications Of Radioactive Tracer Techniques To Pharmacy And Pharmaceutical Research


John E. Christian

"Pharmacy, As A Profession, Is Chiefly The Application Of All Branches Of Science To The Production Of Medicinals And Medicinal Products, And Since Radioactive Isotopes Are Applicable To All Branches Of Science, Isotopes Have Particular Application In The Various Divisions Of The Pharmaceutical Profession. In View Of These Facts, The Pharmaceutical Profession Should Be Quick To Awaken To The Unique Opportunities Afforded."

"Radioactive Isotopes When Used For Therapeutic And Diagnostic Purposes Are In The True Sense Of The Word Drugs And Are So Classified And Regulated Under Section 505 Of The Federal Food, Drug, And Cosmetic Act." "It Is Desirable That In The Future A Greater Number Of Individuals Interested In Pharmaceutical Research And The Welfare Of Pharmacy Make Use Of This Tool."

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Early Nuclear Pharmacy Services

- Located in Large Hospitals
- Limited by Lack of Personnel
- Products Available
  - Long Half-Life Nuclide
  - Final Form
  - Shipped by Industry

Molybdenum/Technetium Generator

- Crude at First
- Improved Generators Made Available
- Changed Nuclear Medicine and Nuclear Pharmacy
Study by Tom Gnau 1969

- Nuclear Medicine Bowman Gray Medical School
- Studied Concept of Shared Nuclear Pharmacy Services
  - Reduce Cost
  - Improve Efficiency
  - Serving Several Nuclear Medicine Facilities
- Successful Outcome
- Foundation for Centralized Nuclear Pharmacies
Early Centralized Nuclear Pharmacies

- University of Washington: David Allen
- University of Tennessee: James F. Cooper
- University of Nebraska: J. William Dirksen
- University of Michigan: Rodney D. Ice
- Indiana University Medical School: Michael P. Kavula
- University of New Mexico: Richard Keesee

M.S. Degree in Radiopharmacy

- Established at USC in 1968
- Walter Wolf and Manual Tubis
- Contributed Recognition and Visibility
- Trained Outstanding Individuals
- Contributing Extensively to the Development of Radiopharmacy
Dr. Richard Keesee

- Early Graduate of USC
- Envisioned a Stand-Alone Radiopharmacy
  - Licensed as a Pharmacy
  - Authorized by Nuclear Regulators to Dispense on Order from a Nuclear Physician
- Dream Fulfilled at the University of New Mexico College of Pharmacy in 1971-1972

University of New Mexico Radiopharmacy Trainees

- Individuals Trained in First Three Years
- Established Centralized Radiopharmacies
Nuclear Pharmacy, Inc
Robert Sanchez & Richard Sakasitz

Pharmatopes, Inc:
Monty Fu & Mark Hebner
Pharmaco Nuclear:
Richard Kessee & David Hurwitz
Centralized Nuclear Pharmacies Today

- Several Corporate Chains
- Significant Number of Independents
- Providing Over a Substantial Percentage of Radiopharmaceutical Doses

Commercial Centralized PET Nuclear Pharmacies

- Increasing in Number Rapidly
- Demand for $^{18}$F-FDG
- Recognition of the Clinical Utility of PET
- Benefiting Patients and Nuclear Medicine
Hospital-Based Nuclear Pharmacy

- Significant Number Serving Nuclear Medicine
- Realization of the Vision of Captain Briner and John E. Christian
- Participating in Clinical Studies, Teaching and Providing Products

Recognition of Nuclear Pharmacy

Motivating Forces

- Need to Promote Harmonization in Practice and Training
- Foster Professional Development
- Regulatory Issues Affecting Practice
- Creation of a Task Force to Establish Mechanisms for Recognition of Specialties in Pharmacy and Certification of Specialists: Spring 1973

Recognition of Nuclear Pharmacy

- Questionnaire to Determine Interest in a Formal Organization
- Selection of the American Pharmaceutical Association (APhA)
- APhA Sponsored Session in Chicago, August 8, 1974
- Petition for Recognition as the Section on Nuclear Pharmacy
- Approved in San Francisco, April 23, 1975
Comments From the Presentation by Dr. Henry Wellman, APhA Annual Meeting in Chicago, 1974

"I Don't Want to See "Radiopharmacy" Degraded to the Point Where Somebody is Just Counting Out Millicuries, If You Will, as Our Pill Counter."

"I Expect Anybody Working with Me Who is Preparing or Responsible for the Preparation of These Radioactive Substances to be Almost as Involved with Them with the Totality of Their Uses as I Am."

"I Want Him (Mike Kavula) to Be Aware of What It Is We Expect Out Of These Studies,.....to Be There and See How They Act."

"And As Far As I'm Concerned, from that Point of View (Pure Food and Drug Act) The Radioactive Substance That We Put in Human Beings are Pharmaceuticals."
Estimated that 60% (120 Individuals) Were Members of the Section on Nuclear Pharmacy

Captain William H. Briner Served on an FDA Radiopharmaceutical Advisory Subcommittee to Study the "Nuclear Pharmacy Issue."

Task Force Within the Conference on Radiation Control Program Directors Had Been Organized "To Review And Evaluate the State of the Art of Nuclear Pharmacy and How It Impacts Existing Radiological Health Regulations."

"The Proposed Model Pharmacy Regulations for Nuclear Pharmacy Contains Several Controversial Issues Such as Space Requirements and an Unprecedented Training and Experience Requirement for the Licensee."  

Educational Affairs Working on a Task Analysis for Nuclear Pharmacy to Be Used for the Petition for the BPS to Describe "Specialized Functions."

A Plan for the Development of the Petition for Recognition as a Specialty was Developed at the Section Officers Meeting on December 14, 1976.  
Assigned Six Task Groups to Address Seven Criteria.
Council on Nuclear Pharmacy

- Appointed by the Board of Pharmaceutical Specialties
- Developed Procedures for an Examination and Scoring
- Developed Requirements to Sit for an Exam
- First Examination Given in Las Vegas and Atlanta, April 24, 1982
- 63 Pharmacists were Designated as Board Certified Nuclear Pharmacists (BCNP)
- Today Hundreds of BCNP’s Serve Nuclear Medicine
Nuclear Pharmacy Today

- Evolved to an Organized Structured Profession
- Enhanced Uniformity and Quality Service through Established Protocols
- Practice and Education Guided by Practice and Training Guidelines
- Patients and Nuclear Medicine Served 24–Hours Daily
- Products Used Occasionally Readily Available
- Efficient Cost Effective Services
A Glimpse Ahead

- Centralized PET Radiopharmaceutical Services Continue Under cGMP
- Commercial Centralized Nuclear Pharmacies Stimulated by Function Indicating Molecular Based Radiopharmaceuticals
- Provide Safe and Cost Effective Services for Therapy Radiopharmaceuticals
- Operate Under Strict SOP and Policies

A Glimpse Ahead

- Change in Physical Facilities and Practice Techniques Resulting from USP Chapter 797
- Operate with Robotic Devices
- Experience Change from Formalized Technician Training
- Exploit Opportunities Afforded by Advancements in Electronic Communication