

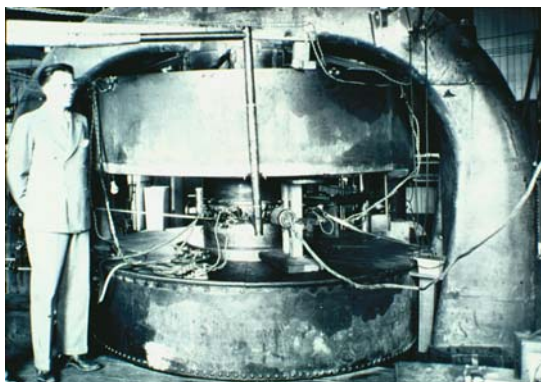
## Epilogue

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Only he who keeps his eye on the far horizon can find the right road. Today, it is widely accepted that the earlier a diagnosis is made, the greater will be the benefit of treatment. Characterization of the extent of disease within the body, called “staging,” helps predict what is going to happen, and helps plan effective treatment. Early demonstration of the effectiveness of treatment soon after it has begun improves care and decreases its cost. Early detection of recurrence at a later time makes possible further treatment and often prolongs the life of the patient.

The first use of a radioactive isotope for the treatment of disease was by Dr. John Lawrence on Christmas Eve, 1936. The first patient suffered from leukemia and was treated with phosphorus-32. The most successful use of P-32 therapy was in the treatment of polycythemia vera, a disease characterized by an increased production of red blood cells. If P-32 was “the first child of radionuclide therapy, treatment with radioiodine in thyroid cancer was the midwife that delivered atomic medicine” to the world. Drs. Joseph Hamilton and Mayo Soley of the University of California San Francisco Medical School were the first to treat hyperthyroid patients with iodine-131, discovered and produced by Dr. Glenn Seaborg at Berkeley. Radionuclide therapy is today having a renaissance in “molecular nuclear medicine,” the new name of nuclear medicine. As long ago as 1978, I wrote: “Because of its chemical and physiological orientation since its beginning, nuclear medicine has had an orientation to drug therapy . . . When it was discovered that ionic gallium-67 accumulated in neoplasms, people began to investigate whether stable gallium might have an anti-neoplastic effect.”

Therapy has been linked to diagnosis since the first human studies were performed with radioactive tracers. In 1936, Karl Compton and his colleagues at the Massachusetts Institute of Technology (MIT) and the Massachusetts General Hospital (MGH) produced small amounts of the radionuclide iodine-128 and examined its accumulation by the thyroid in rabbits. Their results were published in 1938. In 1939, the group working at the University of California at Berkeley used iodine-131 to show that the normal thyroid accumulated radioiodine. It was found that in some patients the accumulation of the tracer, radioactive iodine, was occurring at an abnormally fast rate. This could be reduced by administering larger doses of the same radioisotope which would kill some of the thyroid cells and cure the disease, the birth of radionuclide therapy. Whenever specific molecular processes are defective, as in the basal ganglia of patients with Parkinson disease, drugs such as L-Dopa, can stimulate the deficient process.



**Figure 185** Ernest Lawrence, inventor of the cyclotron.

After World War II, there was great excitement about the use of radioiodine for the treatment of thyroid cancer and hyperthyroidism. The press and public greeted the beginning of the post-war “Atomic Age” as a welcome relief from the atomic bomb. Only a few pioneers believed that some day nuclear medicine would achieve the widespread acceptance that it has today, when, every year, new tracer procedures make it possible to examine molecular processes and physiology in every part of the living human body, characterizing the patient’s problem at the molecular level of organization, more basic than the cellular level of histopathology.

In the United States, researchers from medical institutions, universities, and industry present the results of their research at the annual meeting of the Society of Nuclear Medicine. With strong government support that began immediately after World War II, American companies have made major contributions, and continue to provide leadership. Today, all over the world, hard-working, dedicated and creative people make major contributions.

To be sure, problems persist. One of these is the dependence of the United States on Canada for the production of reactor-produced radionuclides used in medicine and biomedical research. When privately-owned domestic commercial suppliers of radionuclides began operation in the 1960s, the Atomic Energy Commission ceased its production. Private domestic sources in the United States are sorely needed.

Most of the larger companies in nuclear medicine today are multi-national, reflecting the diversity of people in the field since its inception. Mainstream and entrepreneurial instrumentation companies continue to develop “novel imaging” devices. There is ever-increasing capital investment, benefiting patients and the entire health care system. Industry is increasing its collaboration with academic and private research programs, and cooperating with large pharmaceutical companies.

Nuclear medicine is playing an increasingly important role in drug design and the development of pharmaceuticals. Companies rely on radioactive traces and molecular imaging to decrease the time and cost of developing new drugs from the large number of possible compounds developed in basic sciences, including genetics. From the tens of thousands of candidate drugs, nuclear medicine technology helps select the most promising early in the new drug development pathway, and accelerates the extensive developmental and regulatory process until they become accepted as approved drugs. The same

imaging techniques used to validate the diagnostic agent are often used subsequently to select those patients who are likely to benefit from the specific treatment. Then, during the course of treatment, radiotracer studies help monitor the patient's response.

Nuclear medicine is today a multi-billion dollar industry in the United States. Yet more patients could benefit from nuclear medicine procedures than are now receiving them. It has been said that nuclear medicine is "the best kept secret in medicine," but this is no longer the case. The information provided by nuclear medicine is greatly improving the efficiency in the delivery of health care, for example, in the better selection of patients for surgery.

In a report, "Crossing the Quality Chasm," the Institute of Medicine stated: "Our attempts to deliver today's medical capabilities are the medical equivalent of manufacturing microprocessors in a vacuum tube factory. The costs of waste, poor quality and inefficiency are enormous." Nuclear medicine can define diseases at the molecular level for every person. These measurements can help plan specific treatment, monitor its effectiveness, and direct adjustments to treatment when ineffective. This results in more effective, less costly surgical and pharmaceutical therapy.

What we need to do now is decrease the time required to carry out nuclear imaging studies. Fortunately, current research is resulting in procedures and instruments that take less time without reducing quality. Still, on average, it takes about 90 minutes to perform a PET scan, which amounts to about 1,000 studies per year for each scanner. With the new scanners under development, it is possible to perform greater numbers of studies in the same time. For example, several companies, including Hamamatsu Photonics, K.K. have recently built PET scanners that can image the entire human body in less than 10 minutes. Such devices are particularly useful in the screening of large numbers of persons with increased risk of specific diseases, for example, because of a genetic predisposition.

Today, we need to continue to try to relate molecular processes to specific genes (e.g., radioiodine uptake by the thyroid is the result of overactivity of the sodium-iodide "symporter" gene). In sickle cell disease, a genetic abnormality results in an abnormal hemoglobin molecule, which causes increased hemolysis, and the risk of thrombosis. Resistance to chemotherapeutic drugs in the treatment of patients with cancer results from expression of the protein, P-glycoprotein, which transports the chemotherapeutic agent out of the cancer cells. In depressed patients, we can block the sites on the presynaptic neurons that remove the neurotransmitter, serotonin, from the synapse. We can block the dopamine transporter in patients with Parkinson disease, and block the CD20 antigens on malignant cells in patients with non-Hodgkin lymphoma. Radiotracers can define biochemical processes in the brain in order to homogenize patient groups with various mental disorders who are chosen to participate in clinical trials of new drug therapy.

We can assess the effectiveness of gene therapy by examining the effectiveness of viruses used to carry therapeutic genes into injured heart muscle of patients with myocardial infarction. We can quantitatively assess the survival and subsequent division of transplanted cells.

One of the major characteristics of nuclear medicine is that teams of people bring their different technologies to solve patients' problems. Disciplinary boundaries disappear, and are replaced by hybrid domains in which cooperation is the basis of success.

Each specialty brings its own focus of research, and advances are multi-focal. For example, only recently has “molecular imaging” with radioactive tracers been expanded to include optical imaging with fluorescent tracers. Visible light is only a small part of the entire electromagnetic spectrum, comprising wavelengths of 400 to 700 nanometers, part of a spectrum that ranges from gamma rays trillions of times shorter than visible light to radiowaves trillions of times longer.

PET, SPECT, and optical imaging provide new eyes in a world where there is always more to be seen. The greater sensitivity of optical imaging results in a 1,000-fold increase in spatial resolution, which makes possible the application of the tracer principle to study isolated cells *in vitro*. Positron emission tomography (PET) and single photon emission computed tomography (SPECT) make it possible to examine regional function and biochemistry in large experimental animals and human beings in health and disease, while optical imaging provides intracellular imaging. The higher energy photons of PET and SPECT penetrate the human body to permit measurement of radioactive tracers deep within the body.

The president and CEO of General Electric Medical Systems, Joseph M. Hogan stated recently:

“In the years to come, we envision a health care system that uses molecular medicine to diagnose and treat patients before symptoms appear and treatments that are tailored to an individual based on his or her genetic makeup.”

What challenges lie ahead? Most of all we need to simplify the regulatory process for the approval of new radiopharmaceuticals. In November 1987, Dr. John Palmer, director of the division of oncology and radiopharmaceutical drug production of the FDA, called attention to the “regulatory gray area” for the products of in-house cyclotrons. An important difference between diagnostic radiopharmaceuticals and other drugs is that radiotracers are designed to have no biological effect. Therefore we do not need the same regulatory criteria used to assess drugs designed to have biological effects. The term “outcome” has a different meaning when applied to a diagnostic agent, where the product of the procedure is information, not the achievement of a therapeutic effect, as is the case for conventional pharmaceuticals. Often the goal of a diagnostic procedure is to help decide which treatment is likely to counter the disease process or relieve symptoms. Until the late 1970s, the use of radiotracers in medicine was exempt from FDA regulations, without there being any untoward effects during this pre-FDA era. Their use was under the control of institutional Radioactive Drug Research Committees, following the guidelines of the Atomic Energy Commission, and subsequently the Department of Energy. More tailor-made regulations need to be created and implemented by the FDA. Efforts in this direction are already underway. On January 24, 1986, Dr. Ephraim Lieberman, President of Cadema Medical Products, Inc., proposed that for many radiopharmaceuticals, especially in-house PET tracers, the review process could be carried out by selected, qualified academic institutions with all of the credentials and supervision necessary for an effective, timely assessment.

In June 1979, faced with the resignation of Judy Glos, Executive Director of the Society of Nuclear Medicine, who made enormous contributions to its growth and success, I made the following proposal in the *Journal of Nuclear Medicine*:

“I believe the time has come to form a Federation of Societies of Radiological Sciences . . . an analogous structure to the Federated Societies of Experimental Biology

(FASEB) . . . the identity of the individual societies would be retained, as they are in FASEB.

“We must convince the public and political leaders that our technologies, although often expensive, serve to reduce the ‘guesswork’ in medical diagnosis and therefore reduces the costs of delayed or wrong treatment.

“There comes a time when one’s future depend on being aware of one’s problems, being imaginative enough to see solutions, and being courageous enough to take bold steps. This, in my view, is such a time.”

Few people have been given the opportunity to witness the birth and growth of a new medical specialty, increasingly being called “molecular medicine.” No specialty is better suited to meet the challenge of addressing the basic questions that make up the practice of medicine:

1. Where within the body is the patient’s problem?
2. What are the molecular changes within the body related to the patient’s problem?
3. What is going to happen to the patient if the problem is not addressed?
4. What can be done about it?
5. Has the problem persisted after treatment?
6. Has the problem recurred after apparently successful treatment?

Today, molecular medicine is having an enormous effect on health care and is becoming widely known by all health care professionals and an increasingly large part of the public. The specialty has extended the foundation of medicine for over a century, from a time when anatomical and histopathological abnormalities defined disease.

The combination of structural and molecular manifestations by “hybrid” imaging of CT and MRI with PET and SPECT is increasing every day. Today, radiologists and nuclear medicine physicians are becoming expert in structural and molecular imaging, and are becoming qualified as experts in their interpretation.

We are living in what has been called the “Information Age.” It is now possible to have a patient play an increasing role in his or her care as a unique individual. As one molecular process after another can be imaged in every organ of the body, advances in information technology are needed more than ever before. Physicians and patients need full access to the ever-increasing “molecular” information, specific for each patient, in order to be able to make more intelligent use of the health care system. Better knowledge about each patient will lead to better, more effective and more efficient health care. Perhaps within several decades, there will be a vast national network of electronic health records.

While the past half century has witnessed revolutionary advances in chemistry, physics, biology, and medicine, the delivery of health care to the individual patient has changed little. There is increasing use of electronic health records (HER’s), the foundation for a system that can provide all the information about an individual patient’s health and diseases. In the future, each person will have access to a complete, up-to-date review of his or her past and present medical history, manifestations of disease, and medications.



**Figure 186** Alan Maurer, President of the Society of Nuclear Medicine and a former trainee in nuclear medicine at Johns Hopkins, awarding Henry Wagner a citation on the occasion of his presenting the 25th annual Highlights talk at the annual meeting of the Society of Nuclear Medicine.

Today, in 2005, only about 13% of hospitals have adopted electronic health records, (EHR), and this number will undoubtedly increase.

Within the next few decades, everyone will have a periodically updated computer chip (EHR), containing lifetime manifestations of his or her state of health. The individual's health information will be periodically entered into an International Database of Health Manifestations (manifestations include symptoms, physical signs, lab tests, imaging, etc.—all the aspects of life related to health or disease). He or she will be alerted if abnormal manifestations are identified. The health chip will periodically search an International Health Manifestations Database (IHMD) that will help answer the following questions in language that can be easily understood: (1) Is anything wrong? (2) What is going to happen? (3) What can be done about it? And (4) Is the treatment helping? Rather than simply giving a name to a person's disease, the health chip will reveal all aspects of that person's health and illness. The health manifestations on the computer chip will search the IHMD to characterize a disease that may develop, predict what is likely to happen, and suggest possible treatments.

Molecular imaging makes such a system especially necessary because of the coming revolution in health care. Using statistical averaging, a series of PET images can be integrated to yield computer images of "normal" individuals, or patients with different diseases. Okada et al., in a joint effort by Hamamatsu Phototonics (Japan), the University of Washington (Seattle), and the University of Michigan (Ann Arbor), studied an existing



cohort made up of 551 normal individuals and 31 patients with Alzheimer disease (AD). They derived a composite, statistically analyzed distribution of F-18-FDG in the brains of patients with AD.

*In vitro* imaging will be used together with *in vivo* imaging. Genetic profiles will provide information about the risk of the patient's developing one or more diseases in the future, and will be able to suggest possible steps for prevention. Relating genetics to physiologic processes, called "functional genomics," will become increasingly possible, characterizing the relationship between one or more genes and specific homeostatic processes, which can vary greatly from person to person. We will be able to display composite images of different regional molecular states and processes. An example is the imaging of regional distribution of dopamine receptors in different parts of the brain and relating the findings to mental function and diseases.

We need to establish whether the variability among normal persons and patients with different diseases follow a single or multimodal distribution. We need to identify those molecular phenotypes that follow Mendelian genetics, characterize complex homeostatic processes, and identify diversity among normals as well as patients with disease. Study of abnormal molecular processes will identify abnormal genes and proteins.

To create an International Health Manifestation Database (IHMD), we need to continue to create well-defined subsets of images of disease manifestations. We need to enter them into an Internet database, analogous to the "open source" philosophy in computer programming, so that normal and disease databases will be available to all. Eventually, we will be able to compare the patient's anatomical, functional, and biochemical imaging studies with images in the IHMD through co-registration or precise overlay of the database image. Already, in the case of an F-18-FDG PET scan of a patient, the physician can go online and relate the images to a dataset of normal people. This capability will be extended to all diseases.

Molecular imaging, the process of identifying, localizing, and quantifying normal and abnormal regional molecular processes and relating these processes to genotypes, histopathology, and the patient's clinical problems (phenotypes) will characterize medicine in the future. We can no longer rely on a single physician's brain to interpret all the data about the patient including *in vitro* genetic and *in vivo* molecular imaging images. Nuclear medicine has the opportunity to face this challenge.

Is it beyond our wildest dreams to be able to bring this about? Technological advances usually take more than 20 years to reach widespread use. By the end of the decade, every American will have an Electronic Health Record (EHR). Our challenge is to make sure that by 2020, the EHR will contain genetic and molecular imaging information. It is time for a paradigm shift in the practice of medicine. Every person needs to be more closely involved in his or her health care. The principle that "only the doctor knows best" is on the way out.

Until now, the practice of medicine has been managed primarily by physicians, hospital administrators, and insurance companies. The IHMD will give patients an equal role in the operation of the health care system. Patients will be increasingly conscious of the quality and cost of their health care. They will have greater access to information that will permit them to make informed choices. Patients will continue to look to their doctors to advise them and guide them through the complexities of an illness, but the patients will be partners in their care rather than clients. Patients will play an essential

role in maintaining their health and taking care of themselves, with their physician's help when they are sick.

Today, over 70 million persons in the United States get health information from the Internet. We have come a long way since the time of "horse-and-buggy" medicine. The horizon is becoming clearer. Nuclear medicine was the first medical specialty to use computers in the everyday practice of medicine. It can play a key role in helping create whole new model of health care in the 21st century.

We are witnessing a renaissance in radionuclide therapy of cancer. We have "magic bullets" far beyond radioactive iodine and radioactive phosphorus, the patron saints of radioisotope therapy. With the demonstration of the effectiveness of radionuclide therapy in treating non-Hodgkin lymphoma, oncologists will have to become trained in these procedures, just as cardiologists are now trained in nuclear cardiology. Within a decade, radionuclide therapy will have achieved a role equal to surgery in the care of patients with cancer. Not only will there be "molecular diagnosis" of cancer; there will be molecular treatment and monitoring of the effectiveness of therapy.

What the future holds is as uncertain as ever. Looking back, despite the obstacles that they faced, the pioneers of the field of nuclear medicine had a lot of fun. Many were unforgettable personalities, willing to venture beyond well-accepted pathways to profes-

**Figure 187** Professor Karl Oeff, former Head of Nuclear Medicine at the Free University of West Berlin. His technologist, Ursula Scheffel, emigrated to Hopkins nuclear medicine and rose to the rank of Associate Professor.



**Figure 188** Henry N. Wagner, Jr., during a visit to the Max Planck Institute in Berlin in 1961.







**Figure 189** Anne Wagner during a visit to Moscow and Leningrad in 1961, during which she read a lecture of mine on liver scanning in the Russian language.

sional advancement in academic medicine, and face the risk that the dramatic new technology might not achieve their expectations and never become accepted as a new way to define and treat disease. They rejected the admonitions of their superiors who said “think as you are told to think. Do as others do. Learn the rules.” Many of the pioneers in nuclear medicine are no longer living, but those who remain can be very proud.

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# Index

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## A

- Abbott Laboratories, 76, 148
- Abrams, Herbert, 143
- Academic medicine, 56
- Accidents, nuclear, 92, 98
- Acetylcholine, 209
- Acheson, Dean, 82
- Acquired Immune Deficiency Syndrome (AIDS), 107, 230
- ACTH, 208
- Activation analysis, 112
- Adelstein, James, 143, 144, 193
- Administration, 70, 124
- Adrenal hormones, 45, 50–51, 208, 229
- Advanced degree programs (JHU), 122, 141
- Adventures in Radioisotope Research* (Hevesy), 156
- Aebersold, Paul, 80, 82, 83, 84, 125
- Aging, 209
  - cerebral blood flow, 218
  - reticuloendothelial function, 167
- Airway, ciliary clearance, 103
- Alavi, Abass, 202
- Albumin, radiolabeled, 75
  - cardiac imaging, 105, 182, 183, 185, 186, 187
  - early publications, 120, 121
  - lung scans, 99, 167–168, 174
  - pericardial effusion imaging, 111
  - rectilinear scanner studies, 117
- Allen, Woody, 227
- Alvarez, Luis, 7, 8
- Alzheimer's disease/senile dementia, 123, 133, 209, 216, 218
  - genetic factors, 242
  - serotonin receptor imaging, 218
- Ambient radiation, 97–98
- American Board of Internal Medicine (ABIM), 70
- American Board of Nuclear Medicine (ABNM), 78, 133, 180
  - formation of, 70–71
  - residency program establishment, 119
- American Board of Radiology, 180
- American Cancer Society, 120
- American College of Radiology, 71
- American Federation for Clinical Research (AFCR), 52, 140
- American Medical Association (AMA)
  - American Board of Nuclear Medicine approval, 180
  - Department of Computer Systems, 106
  - recognition of nuclear medicine as specialty, 70
  - specialization in nuclear medicine, 71
- American Society for Clinical Investigation (ASCI), 52–53
- Amtey, Sharad R., 197
- Amyloid, 209
- Analytical applications, 111
- ANAQUEST, 124
- Anatomical imaging, 13, 77, 78, 137–138, 149
  - grant applications for development of, 121
  - rectilinear scanners, 117
- Aneurysms, 188
- Anger, Hal, 7, 77, 149, 157–158, 163, 164–165, 185
- Anger camera, 104, 152
  - brain scans, 207, 208
  - cardiac imaging, 106, 181, 182, 183, 185, 193
  - invention of, 163
  - lung scans, 171
  - oncology, 208
  - thyroid scans, 164–165
- Angiocardiology, 181, 186, 188
- Animal studies, 122, 228
  - brain scans, amyloid, 210
  - PET scanners, 228
  - pulmonary embolism, 168–170, 169
- Annexin-5, 190
- Annihilation detection system, 124
- Antibiotic research, 43
- Antibodies
  - cancer detection, 198
  - infectious disease, 229–231
- Anti-diuretic hormone (ADH), 54–55

- Apoptosis, 190  
 Arrhythmias, 190  
 Arteriography, 138, 190  
 Asian Rare Earth (ARE) Company, 94–97  
 Asper, Samuel, 160, 193  
 Association of American Physicians (AAP), 52, 53, 110  
 Asthenia, neurocirculatory, 55  
 Atelectasis, 172  
 Atomic bomb, 5, 9, 36, 164  
 Atomic cocktail, 165  
 Atomic Energy Act, 82  
 Atomic Energy Commission (AEC), 11, 79, 80, 84, 87, 88, 125, 145, 219, 246, 248  
   Aebersold, Paul, 83  
   in-hospital cyclotrons, 129  
 Atomic medicine, 2, 11, 78  
 Atomic testing, 156  
 Atomic weapons, 81, 82  
 Atoms for Peace Program, 99  
 Australian Atomic Energy Commission, 104  
 Automated microbiology, 123, 135, 144, 145, 230–231  
 Autonomic insufficiency, 55  
 Autoradiography, 201, 206, 207, 208  
 Avery, Mel, 48  
 Avid Pharmaceuticals, 209  
 Awards, HNW, 125, 156, 157  
 Axelrod, Julius, 56
- B**
- BacTec (automated microbiology), 123, 135, 144, 145, 230–231  
 Bacteriology, *see* Microbiology  
 Baidoo, Kwamina, 122  
 Baltimore home and neighborhood, 19–22, 29, 31  
 Bard, Phillip, 44  
 Barrett, Anne Collins, *see* Wagner, Anne Barrett  
 Baruch, Bernard, 82  
 Bauman (iodine function), 161  
 Bayesian approaches, 234  
 Becker, Lewis, 180  
 Becquerel, Henri, 65, 68  
 Behavior, brain and, 209, 214–215, 222–223, 228  
 Behavioral studies, HNW early research, 44  
 Beierwaltes, William, 64, 72, 135  
 Bekhtereva, N., 75, 223, 226–227  
 Bell, Alexander Graham, 68  
 Benacerraf, B., 167  
 Bender, Merrill, 70, 107, 180, 232  
 Benzodiazepine receptor studies, 136, 137, 218  
 Berg, Paul, 107  
 Berliner, Robert, 52, 54  
 Bernard, Claude, 55, 64, 217, 223, 235, 239  
 Bert, Paul, 55  
 Beta particles, 126  
 Bethesda Naval Medical Center, 112  
 Bexxar, 204  
 Big Science, 82  
 Bikini atomic tests, 156  
 Biochemistry, 9  
   homeostatic mechanisms, 55–56  
   regional processes, 234–235  
 Bismuth-214, 69  
 Blalock, Alfred, 169  
 Blau, Monte, 83  
 Bleomycin, Co-57, 198  
 Blood disorders, 9, 244  
 Blood flow, myocardial, 105  
 Blood pressure studies, 55–56  
 Blood volume, 55–56  
 Blumgart, Herman, 2, 3, 4, 16, 183  
 Bohr, Niels, 2, 78, 84, 89, 125  
 Bone imaging, 184  
 Bone marrow  
   computer analysis of scans, 179  
   technetium-99m sulfur colloid scans of reticuloendothelial system, 59  
 Bone scans  
   cancer detection, 198–200, 203, 204  
   imaging procedures used at Johns Hopkins in 1964, 111  
   technetium-99m imaging, 64  
 Bourgignon, Michelle, 86  
 Boveri, Theodor, 201  
 Brain scans, 211  
   aging studies, 76–77, 148  
   amyloid, 209–210  
   cancer detection, 201  
   cerebral blood flow, 175, 179  
   cyclotron and PET facility, 213–214  
   development of products for, 141



- dopamine receptors, 210–211; *see also*
    - Dopamine receptor studies
    - goals of research, 214–215
    - interaction with other transmitters, 218
  - dual detectors, 118
  - early publications, 120
  - early trainees specializing in, 146
  - GABA receptors, 218
  - glutamate receptors, 217
  - imaging procedures used at Johns Hopkins
    - in 1964, 111
  - metal complex uptake studies, 142
  - Mind/Brain program, 219–228
  - neurotransmitter-receptor studies, 124, 130, 131, 206–207
  - oncology, 207–208
  - opiate receptor studies, 206, 211, 215–217
  - pharmacology, 206–207
  - positron emission tomography, *see also*
    - Positron emission tomography (PET)
    - F-18 fluorodeoxyglucose synthesis, 109, 130
    - sensitivity and specificity, 217
  - rectilinear scanner studies, 117
  - technetium-99m imaging, 59, 61, 63
  - tracer development, 123
- Brenner, Sydney, 221
- Bristol-Myers, 200
- Britton, Keith, 152
- Britton, Maria, 153
- Brodie, Bernard, 208
- Brody, William, 139, 140
- Bromomercuri-2-hydroxypropane (BMHP), 118
- Brookhaven National Laboratory, 126, 128, 164
  - F-18 fluorodeoxyglucose synthesis, 109
  - Linac Isotope Producer (BLIP), 129
  - PET scanner, first model, 60
  - technetium-99m generator, 58, 60
  - Visiting Committee, 129
- Brown, Harold, 221
- Brownell, Gordon, 129, 208
- Bruce, Marshall, 77, 149
- Buchanan, Judy, 124
- Budget, *see* Costs/economics
- Building projects, construction/infrastructure/facilities, 120
- Bulbocapnine, 44
- Bureaucracy, 135
- Burns, Donald, 134
- C
- Caceres, C., 177
- Cadema Medical Products, 142, 248
- Cadmium telluride detector, 193
- Cai Rusheng, 195
- Calcium-47, 203
- Calutron, 164
- Calvert Hall College (High School), 33–35, 37
- Calvert Hall Country School, 19, 24, 25, 27, 28, 33
- Calvert Hall High School, 24
- Calvin, Melvin, 126
- Camargo, Edwaldo, 134, 144, 145
- Camera, scintillation
  - Anger camera, 157–158; *see also* Anger camera
  - cameras versus scanners, 104
  - cardiac imaging, 183, 185
  - grant applications for development of, 121
  - ICU applications, 138
  - lung scans, early studies, 100, 101
- Camp St. Martin, 22–24
- Cancer/neoplasia/oncology, diagnosis and treatment, 68, 126, 132, 136, 142, 156, 198–204, 244, 250
  - brain scans, 207–208, 218
  - carcinoid/neuroendocrine tumors, 205
  - early publications, 120
  - genetics, 241, 243
  - membrane receptors, 205
  - PET scans, 130
  - rectilinear scanner studies, 117
  - regulatory issues, 247–248
  - thyroid, 165; *see also* Thyroid studies
  - training programs, 135
- Capintec, Inc., 142
- Capital equipment, resource sharing, 197
- Carbon-11, 78, 83, 125, 126, 129, 151, 156, 159
  - brain scans, 77, 148, 207, 208
    - dopamine receptors, 211
    - GABA receptor imaging, 218
    - N-Methyl spiperone (NMSP), C-11, 211
    - opiate receptor studies, 215
    - serotonin receptor imaging, 218
  - lung scans, early studies, 125
  - neurotransmitter-receptor studies, 130, 131

- Carbon-11 (*cont.*)  
 opioid receptor binding studies, 124  
 radiotracers developed in 1980s, 132, 135  
 spiroperidol, 122
- Carbon-14, 9–10, 79, 126, 129  
 intestinal flora studies, 113  
 lactose levels in lactase deficiency, 112  
 quantitative autoradiography, 201  
 vitamin B-12 analysis, 122–123
- Cardiac cycle, 189, 193
- Cardiac motion/cycle, 105–106
- CARDIOKINETICS, Inc., 195
- Cardiology, 77
- Cardiology, nuclear, 85, 105–106, 114, 132, 136, 180–197  
 angiocardigraphy, 181, 186, 188, 190  
 angiography, 181  
 Bayesian approaches, 234  
 categories of techniques, 185  
 Chinese trip, 193–196  
 development of products for, 141  
 drug effects on left ventricular function, 193  
 early publications, 120  
 early studies and presentations, 105–106  
 early tracer experiments, 69  
 early trainees specializing in, 145, 146  
 ECG-synchronized, 105  
 establishment of programs, 180  
 fluorodeoxyglucose imaging, 130  
 lung scans in, 174–175  
 myocardial blood flow studies, 184  
 myocardial infarction, 184  
 myocardial perfusion, 184–185  
 nuclear stethoscope, 190, 191, 192, 193–196  
 pediatric, 186  
 pericardial effusion imaging, 111, 183  
 screening for arteriography, 138–139  
 summary of capabilities, 189  
 technetium-99m imaging, 63  
 ventriculography/ventricular function, 181, 185, 187, 188–189, 190, 192
- Cardiomyopathy, 181
- Cardiopulmonary bypass, 171
- Carfentanil, 124, 132, 215
- Carlsson, Arvid, 210
- Carlyle, Thomas, 80
- Carnegie Institute, 128
- Carotid circulation, 208
- Carpenter, James W.J., 70
- Carpenter, Will, 146
- Carter, Jimmy, 76, 147
- Cassen, Benedict, 61, 162, 163, 164
- Catecholamines, 208
- Catheterization, cardiac, 183
- Cayetano, Ben, 225
- Celera Genomics, 107
- Center for the Advancement of Radiation Education and Research (CARER), JHU, 92–94, 124
- Cerebral blood flow, 175, 179, 208, 218
- Certificate of Need, 135
- Certification of physicians, 71, 180
- Cesium-131, 184
- Cesium-137, 94
- Chain reaction, 8
- Chamberlain, W., 77, 149
- Chatin (thyroid studies), 162
- Cheliah, R., 96
- Chemical messengers, *see also* Neuroscience
- Chemists, 134
- Chen, David, 134
- Chen, Marianne, 144
- Cheng, Tsung O., 193
- Chernobyl, 92, 93, 94, 97
- Cherry, Simon, 228
- Chiba University, 112, 159
- Childs, Donald S., 70
- China, 192, 193–196
- Chinese herbal medicines, 193, 194, 195
- Chlormerodrin, Hg-203, 61, 111, 143
- Chromium-51, 83, 156  
 albumin aggregates, 75  
 lung scans, 169  
 lung scans, early studies, 99
- Chronic pain conditions, 130, 216
- Churchill, Colin, 42
- Churchill, Winston, 6
- Circulation time, 2, 3, 4, 16
- Civelek, Cahid, 85, 145, 146
- CLINCOM SYSTEM, 106
- Clinical applications  
 PET scans, 129  
 regulatory issues, 219  
 satellite operations in surgical ICU, 145
- Clinical Center, National Institutes of Health (NIH), 52
- Clinical clerkship, 12
- Clinical pathological conferences, 46
- Clinical research, National Institutes of Health (NIH), 56

- Cloud chamber, 68  
Cobalt-57, 198  
Cobalt-60, 77, 83, 156  
Cockcroft, John, 6  
Coel, Mark, 225  
Coindet, J.C., 162  
Colby College, Maine, 116, 117, 173, 175  
Cold War, 10, 14, 44, 90, 98  
Colloidal gold, 117  
Colloidal particles, 119, 120  
Commercial exhibits, World Congresses, 76  
Commercial production of radionuclides, 125, 141, 246; *see also specific corporations*  
Committee chairmanships, 197  
Compartmental localization studies, 111  
Compton, Arthur, 9  
Compton, Karl, 244  
Computed tomography, 77, 78, 138, 149, 196, 196–197, 236  
    brain scans, 207  
    cancer detection, 204  
    hybrid imaging, *see* Anatomical imaging  
    SPECT, *see* SPECT (single photon emission computed tomography)  
Computer analysis, 176–179  
    cardiac imaging, 106, 181  
    early developments, 106–107  
    lung scans, early studies, 102, 103, 104  
Computer-assisted diagnosis, cardiology, 195  
Computerized monitoring of animal activity, 122  
Computer storage of data  
    cardiac imaging, 188  
    International Health Manifestation Database (IHMD), 249–250  
Conant, Jennet, 7, 9  
Congenital heart disease, 174–175, 184  
Congresses and professional meetings, 52; *see also* World Congresses and meetings  
Congressional oversight and regulatory function, 79  
Conjoint Board, 70  
Constantanides, Constantine, 74  
Construction/infrastructure/facilities, 120  
Conti, Peter S., 143, 144  
Conway, James, 116  
Cooper, Malcolm, 188  
Copper-64, 107  
Coronary circulation and myocardial blood flow, 105, 190  
    angiocardiography, 181, 186, 188  
    myocardial perfusion, 105–106  
    ventriculography, 188–189  
Corticosteroids, 50–51, 229  
Cosmic ray radiation, 97–98  
Costs/economics, 181; *see also* Funding, research; Grant applications  
    Anger camera, 158  
    clinical applications, 138–139  
    cost of clinical studies and cost containment, 132–133  
    cyclotron and PET facility, 132  
    drug design and development, 218–219  
    health care, 248  
    Japanese nuclear medicine laboratory budget, 159  
    product development budget, 141–142  
    toxicology studies, 145  
    world congresses, 76, 151  
Cotzias, George, 110, 129  
Courses, *see* Training programs and courses, nuclear medicine  
Courtesy Associates, 76, 148  
Courtois, M., 162  
Cretinism, 162  
Crick, Francis, 80, 107, 241  
Cuaron, Alfredo, 144  
Curare, 131, 214  
Curie, Irene, 6, 66, 67  
Curie, Marie Sklodowska, 65, 66  
Curie, Pierre, 65–68  
Current Procedural Terminology (CPT) codes, 106  
Cyclotron Corporation, 130, 131, 136–137  
Cyclotrons, 2, 6, 7–8, 9, 64, 82–83, 125, 126, 127, 128, 129, 130, 136, 213  
    brain chemistry studies, 131  
    costs, 133  
    dedication program, 135–136  
    early commercial start-up company, 159  
    equipment acquisition, 130–131  
    invention of, 5  
    Japanese, prewar, 88–90  
    Medical Research Council, Hammersmith, 58  
    nuclides produced by, 78

- Cyclotrons (*cont.*)  
 Ohio State University, 125, 151  
 regulatory issues, 247
- D**
- Dale, Henry H., 214  
 Dannals, Robert, 122, 138  
 Database, International Health Manifestation (IHMD), 249–250  
 Data processing, 121, 178, 189  
 Davies, Peter, 209  
 Davy, Humphrey, 162  
 Decay type, 126  
 DeChiro, Giovanni, 201, 202, 208  
 Defense Waste Process Facility, 87  
 Degrees, honorary, 140  
 Deland, Frank, 144  
 Dementia, 136  
 Departmental issues, nuclear medicine, 70–71, 120  
 Deprenyl, 132  
 Derrick, John, 57  
 Detectors, 12, 119  
 annihilation detection system, 124  
 brain scans, 207, 208, 217  
 cadmium telluride, 193  
 cameras versus scanners, 104  
 cardiac imaging, 183, 188  
 Cutie Pie radiation monitor, 112  
 dual, 118  
 early devices, 65, 68  
 gamma cameras, 85  
 grant applications for development of, 121  
 lung scans, early studies, 100, 101  
 presentation to Japan, 1954, 90  
 thyroid scans, 161, 162–163  
 Dexetamide, 132  
 Diabetes insipidus, 54–55  
 Diagnosis  
 computer-assisted (CAD), 195  
 integrated approach to medicine, 232–240  
 Diagnostic and Therapeutic Technology Assessment Panel (DATTA), 180  
 Diagnostic applications, 244  
 anatomical imaging, 78  
 cancer detection, 198  
 cardiac imaging, 185  
 computers, early developments, 106–107  
 early developments, 69–70  
 early trainees, 143  
 grant applications for development of, 121  
 psychiatry, 213  
 regulation and economics, 145  
 regulatory issues, 247–248  
 review committee, 132  
 Diagnostic Isotopes, 142  
 Dibos, Pablo, 134  
 Digital Equipment Corporation (DEC), 106, 178  
 Diprenorphine, 123, 130, 132, 215  
 Dirty bombs, 98  
 Disciplinary boundaries, 14, 70–71, 120, 139, 247  
 Distribution of radionuclides, 125  
 DNA, 80, 97, 107, 200  
 Doan, Charles, 72, 158  
 Donner, Martin, 133, 135, 136, 197  
 Donner Laboratory, 78–79, 151, 156, 164  
 Dopamine receptor studies, 122, 124, 136, 137, 204, 206, 210–211, 212, 213, 217  
 goals of research, 214–215  
 interaction with other transmitters, 218  
 Parkinson's disease, 218  
 Dosage issues, 92, 97–98, 145  
 Douglass, Kenneth, 134  
 Douglass, Terry D., 214, 228  
 Doxepin, 132  
 Drexel University, Herman Block Wagner Chair in Chemistry, 24  
 Drug abuse/addiction, 207, 211, 216  
 Drugs, *see* Pharmacology/drug studies  
 DuBridge, Lee, 8, 9  
 Duelfer, Tim, 134  
 Duesberg, Peter, 201  
 Duncker, Carlos Martinez, 145  
 Dunham, Charles, 77, 149  
 Dupkin, Carol, 224  
 Dupkin, Manuel, 140, 223, 224  
 Dyes, I-131 Rose Bengal, 110, 111
- E**
- Economics, *see* Costs/economics; Funding, research  
 Ectopic thyroid tissue, 163–164, 165  
 Editorial board appointments, 197  
 Effort syndrome, 55  
 Egypt, 85  
 Ehrlich, Paul, 131  
 Einstein, A., 7, 64, 98, 227  
 Eisenbud, M., 90

- Eisenhower, Dwight, 79, 80–81, 82, 84–85  
Eisenhower, Milton, 225  
Ejection fraction, 106  
Elbaradei, Mohamed, 99  
Electrocardiography, 105, 181, 183, 185, 188–189, 190  
Electrochemical analysis, 122  
Electronic health records (EHR), 249–250  
Electroscope, 68  
Eli Lilly & Co., 209  
Elkins, William, 17–18  
Emission properties, factors affecting utility, 126  
Emphysema, 171, 172  
Endemic goiter, 64, 162  
Endocrinology, 45, 123, 208  
    carcinoid/neuroendocrine tumors, 205  
    CNS releasing factors, 209  
    early research, HNW, 39–40  
    hormones, brain, and behavior, 228  
    infectious disease and, 229  
Energy, emission, 126  
Energy Research and Development Agency (ERDA), 84, 145  
Enforcement of atomic energy regulations, 82  
Ephedrine, 195  
Epilepsy, 136  
Epilepsy/seizure disorders, 214, 217, 218  
Epinephrine, 208  
Equipment acquisition, 130–131, 139, 197  
Erlich, Paul, 210  
Erythropoietin, 78  
Ethical issues, 181  
European travel, 56–57  
Evans, Robley, 5  
Exhibit space, 76  
Exposure studies, 112, 145  
Extracellular fluid volume, 55–56
- F**  
Facility construction/infrastructure, 120  
Fallout, nuclear, 88  
Feinendegen, Ludwig, 86  
Fermi, Enrico, 5, 7, 8, 78, 126  
Film exposure, 65  
Fisher, A.M., 43  
Fleisher, Alan, 159  
Fleming, William, 203  
Fluorescent tracers, 234–235, 247  
Fluorine-18, 78, 126, 129, 151  
    amyloid plaque-binding by tracer, 209  
    brain scans, 77, 110, 148, 149, 208  
    flurodeoxyglucose  
        biological function, 201–203  
        brain scans, 208  
        cancer cell metabolism, 202–204  
        cancer detection, 201, 202  
        clinical applications, 214  
        early studies, 207  
        synthesis of, 109, 130, 132  
    infectious disease applications, 230  
    thymidine analog, 18-FLL, 204  
Fluorometric studies, 122  
Fogarty, John, 13  
Fracture healing, 143  
Franck, James, 81  
Franklin, Jon, 211  
Fraser, Russell, 12, 58, 160  
Frederickson, Donald, 76, 147  
Friedman, Barry, 134  
Friendly, Alfred, 82  
Frost, James, 122, 145, 216, 217  
Fulbright, William, 223  
Functional genomics, 250  
Functional imaging, 178, 185  
Functional magnetic resonance imaging, 77  
Funding, clinical programs, 119, 134, 139  
Funding, research, 82, 136  
    clinical applications, 135  
    cyclotron acquisition, 136–137  
    cyclotron and PET facility, 213–214  
    government support after WW II, 245  
    Nuclear Instrumentation and Chemistry in  
        Medicine program, 119, 120  
    Pfizer, 43  
    rectilinear scanner acquisition and  
        development, 107  
    scanner construction, 121–122  
Funding, training programs, 85  
Funding, world congresses, 76, 148
- G**  
GABA receptors, 218  
Gaintner, Richard, 133  
Gall bladder function, 179  
Gallium-67, 198, 199, 229, 244  
Gallium-68, 204  
Gambino, R.S., 71  
Gamma cameras, 85, 188; *see also* Anger camera



- Gamma ray spectrometer, 119
- Gang Huang, 196
- Gantt, Horsley, 40
- Gated blood pool images, 106
- Gayler, Bob, 135
- Geberaku (thyroid disease), 161
- Geiger-Muller tube/Geiger counter, 13, 68, 156, 161
- Generators/radioisotope cow, 126, 164
  - Brookhaven National Laboratory, 58, 60
  - molybdenum-99/technetium-99m, 193–196
  - positron emitters, 126
  - rubidium-81/krypton-81m, 208
  - tellurium-132/iodine-132, 58
- Genetic diseases, 55, 107
  - cancer/carcinogenesis, 200, 201
  - integrated approach to medicine, 238–239
- Genetic effects, zero-threshold hypothesis, 97
- Genetic engineering, 107
- Genetics, 227, 228, 235, 241–243, 246–247, 250
- Genome mapping, 87–88, 107
- Genomics, 201, 247
- Genotype, 227, 228
- George, Fred, 156
- Geriatric Nuclear Medicine, 76–77, 148
- Gibbs, W. Wayt, 201
- Gill, Dato, 96
- Glaxo Smith Kline, 200, 218–219
- Gleevec, 200
- Glickson, Jerry, 197
- Glos, Judy, 76, 148
- Glutamate receptors, 217
- Goiter
  - endemic, 64
  - multinodular, 165
  - Pliny the Elder on, 161
  - substernal, 163–164
  - treatment, 12th century, 162
- Gold, colloidal, 117
- Gold-198, 83, 156
- Golden, A.W.D., 12
- Gold leaf electroscope, 68
- Goodof, Irving, 116
- Goodwin, David, 144
- Gottshalk, Alex, 58, 117
- Government regulation, 79
- Graduate degree programs, JHU, 122, 135, 141
- Graduate students, 145
- Graham, Evarts, 171
- Grant applications
  - Biodistribution and Kinetics of Receptors in Human Brain, 131
  - Multi-User Application for Specialized Research Equipment, 130, 131
  - Nuclear Instrumentation and Chemistry in Medicine program, 120
  - peer review policy, 53–54
  - Short Lived Radionuclides in Biomedical Research, 128
- Grants, *see* Funding, research
- Graves (thyroid disease), 162
- Gray, George W., 32, 51
- Gray, Hal, 126
- Green, Allan, 189
- Green, Michael, 105
- Greengard, Paul, 210
- Gromyko, Andre, 82
- Gross (thyroid studies), 162
- Guilarte, Tomas, 122–123
- Guillemin, Roger, 205, 209
- Gumma University, 77, 149
- H**
- Half-lives, 126
- Hamakita Research Park, 228
- Hamamatsu Photonics, K.K., 220, 221–222, 223, 246
- Hamilton, Joseph, 244
- Hammersmith Hospital, London, 12, 14, 57–59, 64, 126, 164
- Hanlon, C. Rollins, 171
- Hansen, William, 8
- Harley, J., 90
- Harper, Paul, 58, 59, 61, 164
- Harris, Craig, 117, 118
- Harvey, A.M., 47–48, 119, 120, 140
- Harvey, Elizabeth, 49
- Harvey, Mac, 11
- Hawking, Stephen, 125
- Hay, Betty, 48
- Health care, 250
- Heart imaging, *see also* Cardiology, nuclear
  - ECG-synchronized, 105
  - fluorodeoxyglucose, 130
- Heart Institute, National Institutes of Health (NIH), 54
- Heisenberg, Werner, 233–234
- Hematological disease, 9, 244
- Hemodynamics
  - circulation time, 2, 3, 16

- early tracer experiments, 69
  - imaging procedures used at Johns Hopkins
    - in 1964, 111
    - myocardial blood flow studies, 105
    - orthostatic hypotension, 55
  - Henderson, Donald A., 226
  - Herbal medicines, Chinese, 193, 194, 195
  - Herceptin, 200, 241
  - Hevesy, Georg, 2, 3, 5, 68, 69, 78, 156
  - Heyssel, Robert, 119, 121, 131, 132, 135, 138, 211
  - Higenamine, 195
  - High school, HNW, 32–35
  - Hilal, Sadik, 136
  - Hill, Lister, 13, 90, 91, 140
  - Hiroshima, 9, 81, 88–89
  - Hiruma, Teruo, 220, 221–222, 223, 225, 226
  - Hisada, Professor, 159
  - HIV/AIDS, 230
  - Hodgkin's disease, 198
  - Hogan, Joseph, 247
  - Holder, Lawrence, 134
  - Holifield, Chet, 88
  - Holmes, Richard A., 143, 144
  - Holter, Joseph, 80
  - Homeostasis, 55–56
  - Honorary degrees, 140
  - Hormesis, 143
  - Hormones, 208
  - Hospital cyclotrons, 129
  - Hounsfield, G., 123
  - House staff training, 11, 56
  - Human Frontier Science Program, 221
  - Human Genome Project, 11, 87–88, 107, 243
  - Humphrey, Hubert, 90, 91, 140
  - Huntington's disease, 107, 130
  - Hurley, Peter, 144, 184–185
  - Hybrid imaging, 248; *see also* Anatomical imaging
  - Hydrocephalus, 208
  - Hydrocortisone, 50–51, 229
  - Hypertension, 179
  - Hypotension, orthostatic, 55
  - Hypothalamic factors, 209
- I
- Ido, T., 207
  - Iio, Mashahiro, 59, 71, 73, 75, 76, 77, 144, 146, 147, 148–149, 159, 167, 168, 185
  - Iio, Mrs. Mashahiro, 73
  - Ilgin, Nese, 123
  - Image Display and Analysis (IDA), 102, 103, 104, 178, 179
    - cardiac imaging, 105, 186, 187
    - lung scans, 173
  - Imaging, *see* Anger camera; Detectors; Gamma cameras
  - Immune system, infectious disease, 229–231
  - IND classification, 219
  - India, 129
  - Indian/American Society of Nuclear Medicine, 129
  - Indian trainees, 123
  - Indium-111, 59, 198, 199, 229
  - Indium-113m, 59, 119
  - Individuals, normal values establishment of, 250
  - Industrial affiliates committee, 76
  - Industrial/commercial production of
    - radionuclides, 125, 141, 246; *see also specific corporations*
  - Industrial/commercial support and
    - collaboration, 119, 141–142, 148, 245
    - drug design and development, 200
    - world congresses, 76, 151
  - Infectious disease, 229–231
    - antibiotic research, HNW, 43
    - early publications, HNW, 50–51
    - early trainees specializing in, 144, 145
    - reticuloendothelial function, 167, 168
  - INFORMATEK, 106
  - Information storage and retrieval, 249–250
  - Inspections, weapons control, 99
  - Institute for Electrical and Electronic Engineers, 106–107
  - Instrumentation, 119; *see also* Detectors
    - grant applications for development of, 121
    - research and development needs, 246
  - Insulin, 208
  - Integrated approach to medicine, 232–240
  - Integrated review group, National Institutes of Health (NIH), 53
  - Intensive care unit
    - cardiac imaging, 193
    - satellite operations in surgical ICU, 145
    - scintillation camera in, 138
  - Interdisciplinary Committee on Nuclear Magnetic Resonance (ICNMR), 197
  - Internal medicine, 14, 70–71
  - International Atomic Energy Agency, 81, 84, 85, 87, 98, 99, 102

- International Health Manifestation Database (IHMD), 249–250
- Intestinal bacteria studies, 113
- In vitro* imaging/laboratory applications, 78, 111, 135, 145
- Iodine
- discovery of, 162
  - physiological function, 161, 162
  - thyroid disease treatment, early developments, 69
- Iodine-121, 156
- Iodine-122, 126
- Iodine-123, 83, 126, 156, 165, 207
- Iodine-124, 151
- Iodine-125, 83, 156, 198
- Iodine-128, 244
- Iodine-131, 141, 156, 244
- albumin tagged with, 61, 75
  - Bethesda training course, 112
  - brain scans, 63
  - cardiac imaging, 182, 184
  - dosage requirements for detection, 165
  - early publications, 120, 121
  - liver scans, 110–111
  - lung scans, 99, 169
  - orthoiodohippurate, 158
  - production of by Livingood and Seaborg, 162
  - rectilinear scanner studies, 117
  - Yamashita group, early studies, 77
- Iodine-132, 126
- distillation of, 164
  - Medical Research Council's cyclotron, 58
- Iodine scans, 12, 117, 160–166
- cancer detection, 198, 203
  - computer analysis, 179
  - detectors, 13
  - early publications, 120
- Iodobenzamine, 132
- Iodoquine, I-125, 198
- Iran, 99
- Iron, red cell labeling, 79
- Iron-52, 126, 151
- Isoproterenol, 195
- Itoh, Harumi, 186
- Iwabuchi, Mr., 159
- J**
- James, William, 209, 222
- Jansen, Carl, 193
- Japan, 77, 112, 113, 114, 115, 146, 159
- cyclotrons, prewar, 88–90
  - First World Congress of WFNMB, 71, 73
  - Hiroshima, 81
  - Mind/Brain program, 219–228
  - nuclear medicine establishment in, 75
  - program development in, 149
  - World Congresses, 147
- Japanese trainees, 112, 113, 114, 115, 146, 185, 186
- Johns Hopkins University, 19
- appointment to professorship, 126
  - Center for the Advancement of Radiation Education and Research (CARER), JHU, 92–94, 124
  - Colby summer course, 117
  - cyclotron and PET facility, 131
  - equipment acquisition, 130–131
  - establishment of nuclear medicine program, 119–120
  - foundation of, 12
  - Henry W. Wagner Jr. Professorship in Nuclear Medicine, 24, 25
  - imaging procedures used in 1964, 111
  - medical school experiences, HNW, 40–41, 46–47
  - Mind/Brain Institute proposal, 223–224
  - Nuclear Medicine Division, foundation of, 14
  - nuclear medicine faculty, 212, 216
  - Osler Medical Service, JHH, 11, 44
  - Radioactive Drug Search Committee (RDRC), 145
  - rectilinear scanner acquisition and development, 107, 117, 118
  - research function, 54
  - residency program establishment, 119
  - School of Advanced International Studies, 227
  - School of Public Health, Department of Radiological Science establishment, 122, 134
  - technetium-99m imaging, 59, 61
  - thyroid scans, 63
  - trainees, 77, 85, 86, 112, 113, 115, 116
  - undergraduate education at, 35–36, 37, 38
  - video system for cardiology training, 195
- Johnson, Lyndon, 90
- Joint Committee on Atomic Energy, 88
- Joliot, Frederik, 6, 67

- Jones, Bob, 169  
*Journal of the American Medical Association, Medical Radioisotope Scanning* (1960), 110–111
- K**
- Kaihara, Shige, 150, 178, 185  
 Kamen, Martin D., 9–10  
 Kandel, Eric, 210  
 Kao, P.F., 196  
 Karmen, Arthur, 141  
 Kato, Mrs. Sadataki, 73  
 Kato, Sadataki, 71, 73, 146  
 Kay, Jerry, 49  
 Keio University, 77, 149  
 Kellersohn, Claude, 149  
 Kendell, E.C., 162  
 Kennedy, Thomas, 52  
 Kerry, Luther, 85  
 Khan, Abdul Qadeer, 98–99  
 Kidney scans, 141  
   Anger camera applications, 158  
   computer analysis, 179  
   dual detectors, 118  
   early trainees, 143  
   Hg-203 chloromerodrin, 111  
   imaging procedures used at Johns Hopkins in 1964, 111  
   rectilinear scanner studies, 117  
 Kidney studies, National Institutes of Health, 54–55  
 Kidney transplants, technetium-99m imaging, 64  
 Kieffer, Julio, 144  
 Kim, Stanley, 123–124  
 King, E. Richard, 70, 180  
 Kinoshita, F., 77, 149  
 Kirschner, Peter T., 143, 144  
 Klystron tube, 8  
 Knock-out mice, 235  
 Knudson, Mary, 216  
 Koestler, Arthur, 137, 207  
 Konishi, Dr. (Kyoto University), 115  
 Korean War, 43–44  
 Kramer, Al, 134  
 Krevans, Julius, 77, 119, 148  
 Kriss, Joseph, 174  
 Krypton-81m, 208  
 Krypton-85, 175  
 Kuhar, Michael, 206, 210  
 Kuhl, David, 70, 103–104, 107, 109, 117, 132, 133, 136, 207, 214, 232  
 Kumpa, Peter, 213  
 Kuramitsu, I., 77, 149  
 Kuranz, John, 152, 165  
 Kyoto University, Japan, 115, 159
- L**
- Laboratory medicine, 85, 111, 135, 145  
 Lactoferrin, 229  
 Lactose intolerance, 112  
 LaFrance, Norman, 144, 145  
 Lang, Daniel, 11  
 Langan, James, 108, 116, 124, 144  
 Langley, Paul, 131, 210  
 Larson, Steve, 116, 142, 144  
 Lathrup, Catherine, 58  
 Laughlin, John, 129  
 Lauterbur, Paul, 197, 228  
 Lawrence, Ernest, 2, 5, 6, 7, 8–9, 78, 81, 82, 83, 125, 128, 151, 162, 245  
 Lawrence, John, 8, 9, 78, 78–79, 80, 151, 244  
 L-Dopa, 129, 204, 210, 244  
 Lead, 68, 69  
 Lebowitz, Elliot, 188  
 Lee, Munho, 73  
 Legislation, 79, 82  
 Lehmann, Carl, 64  
*Lehrbuch der physiologischen Chemie* (Lehman), 64  
 Leibnitz, G. von, 234  
 Leprosy, 145  
 Leukemia, 69, 78, 200, 205, 244  
 Leukocyte labeling, 230  
 Lever, Susan, 134, 142  
 Levetamide, 132  
 Levodopa, 129, 204, 210, 244  
 Li, Ruhleng, 201  
 Libby, Willard, 11  
 Libya, 99  
 Lieberman, Ephraim, 142, 144, 248  
 Lilienthal, David, 82  
 Limulus test, 231  
 Links, Jonathon, 122, 134, 143, 144  
 Lithium, 218  
 Liu Xiujie, 192, 194, 195, 196  
 Liver scans  
   cancer detection, 198, 199  
   colloidal particles, 119  
   early publications, 110–111, 120

- Liver scans (*cont.*)  
 imaging procedures used at Johns Hopkins  
 in 1964, 111  
 iodine-131 Rose Bengal, 110  
 rectilinear scanner studies, 117  
 technetium-99m, 59, 64
- Livingood, John, 162
- Loewi, Otto, 209
- Longstrom, Bengt, 94, 97, 144, 211, 212
- Loomis, Arthur, 7, 8
- Lung scans, 75, 167–175  
 albumin microspheres, 174  
 C-11 carbonates, 125  
 cancer detection, 198  
 chronic obstructive lung disease,  
 171–172  
 computer analysis, 179  
 congenital heart disease, 174–175  
 early studies and presentations,  
 99–102  
 pulmonary embolism, 168–171  
 pulmonary perfusion and ventilation  
 function, 171, 172–173, 174  
 technetium-99m imaging, 63, 64
- Lymphoma, 198, 204, 243
- Lysergic acid diethylamide (LSD), 218
- M**
- Maass, Roberto, 144
- MacArthur, Douglas, 88–89
- MacIntyre, J., 76, 148
- Magnetic resonance imaging, 77, 78, 149,  
 196–197, 236, 248  
 brain scans, 206, 207, 228  
 Mind/Brain Institute proposal, 224
- Maisey, Michael, 123, 144
- Maisterrena, Jorge A., 144
- Ma Jixiao, 196
- Malaysian waste disposal site, 94–97
- Mallard, John, 58, 126, 128, 164
- Malmud, Leon, 144
- Manganese-52m, 126
- Manhattan Project, 5, 9, 79, 87
- Manufacturing and production, *see* Industrial/  
 commercial production of  
 radionuclides; Industrial/commercial  
 support and collaboration
- Mao-Song Jiang, 196
- Marine, David, 162
- Massachusetts General Hospital, 129, 244
- Massachusetts Institute of Technology (MIT),  
 7, 8, 9, 244
- Mathematical modeling of dopamine receptor  
 density, 137
- Matson, Ed, 76, 148
- Mattison, Wilbur, 12, 51
- Maurer, Alan, 134, 143
- Mayberg, Helen, 146
- McAfee, John G., 12, 14, 107, 110, 120, 144
- McCarthy hearings, 44
- McIntyre, Patricia, 134
- McKusick, Kenneth, 143, 144
- McMillan, Edwin, 8
- McNeil, Barbara, 143
- McQueen, Donald, 107
- Medical records, 249–250
- Medical Research Council, Hammersmith, 12,  
 58
- Medical school, HNW, 40–41, 46–47
- Medical students, 123
- Medvedev, Dr., 154
- Meetings and congresses, 52; *see also* World  
 Congresses and meetings
- Mehring, Mary Lou, 124, 144
- Memorial Sloan-Kettering Cancer Center, 129,  
 142, 159
- Memory, 210
- Mentors and trainees, *see* Trainees and  
 mentors
- Mercaptoethyl amine-Tc-99m complexes, 141
- Merck, 134, 200
- Mercury-203, 208
- Mercury-203 chlormerodrin, 61, 111, 143
- Mercury-labeled bromomercuri-2-  
 hydroxypropane (BMHP), 118
- Metal complexes, brain uptake, 142
- Methionine, C-11, 132
- Methyl bromo LSD, 132
- Methylketanserine, 132
- Methylspiperone, 132, 135, 211, 212, 218
- Meyer, Adolph, 39
- Microbiology, 123, 135, 144, 145, 230–231
- Microdialysis studies, 122
- Microspheres, albumin, 174
- Milieu interieur*, 55
- Military control of atomic energy, 79
- Milk (in)tolerance, 112
- Mind/Brain study program, 211, 219–228
- Mineral nutrition studies, 111
- Min-Fu Tsan, 134



- Minicomputers, *see* Computer analysis
- Mitchell, Thomas, 134, 143
- MMM (3M), 76, 148
- Mohamadiyah, Mohammed, 123
- Molecular biology, 107
- Molecular communication, *see* Neuroscience
- Molecular imaging, 64, 78, 247, 250
- Molecular medicine, 71, 232–240
- Molybdenum-99, 58, 141, 164
- Molybdenum/technetium-99m generator,  
China trip, 193–196
- Monitoring, Asian Rare Earth (ARE)  
Company, 96
- Monitors/monitoring, radiation  
Bethesda training course, 112  
Cutie Pie, 112  
detectors, *see* Detectors  
International Atomic Energy Agency, 99
- Monozoite, 94–95
- Montana Society of Nuclear Medicine, 80
- Moody, Nellie, 49
- Moorhead, Caroline, 214
- Moreno, Jose, 144
- Morgan, Russell, 122, 141
- Morning conference, JHU, 113
- Morphine, 215
- Moses, David, 134
- Moss, William T., 70
- Motion display, cardiac imaging, 185
- Mountcastle, Vernon, 44
- Mozley, James, 107, 110–111
- Muller, President of JHU, 224, 225
- Murphy, Frank, 15
- Muscarinic cholinergic receptor studies, 137,  
218
- Muscle blood flow, 175
- Mushararaf, Pervez, 99
- Muto, Pietro, 75
- Mycobacterial infections, 145
- Myers, Jack D., 70
- Myers, William G., 71, 72, 73, 83, 84, 125, 151,  
156–159
- Myocardial blood flow studies, *see* Coronary  
circulation and myocardial blood flow
- Myocardial infarction, 120, 181, 183, 184, 188
- Myxedema, 162
- N**
- Nader, Ralph, 79
- Nagai, T., 77, 149
- Nagasaki, 9, 36
- Nagoya University, 77, 149
- Nalmefin, 124, 217
- Naloxone, 124, 215
- NanoDx probes, 232
- Natarajan, T.K., 172, 178
- Nathans, Daniel, 107
- National Health Services, British, 58
- National Institute of Radiological Sciences,  
77
- National Institutes of Health (NIH), 11, 52–56  
blood pressure studies, 55–56  
cardiac imaging, 105  
cyclotron funding, 213  
funding of early programs, 120, 122, 136  
funding of Nuclear Instrumentation and  
Chemistry in Medicine program,  
119  
gene therapy, 107  
Human Genome Project, 87–88  
Institute of Arthritis and Metabolic  
Diseases, 13  
kidney studies, 54–55  
National Heart Institute, 210  
National Institutes of Biomedical Imaging  
and Bioengineering (NIBIB), 1  
peer review policy, 53–54  
physiological approach to disease, 54–55  
twenty-first century research goals, 1
- Natriuretic peptide, 195
- Naval Medical Center, Bethesda, 112
- Nealen, Joseph P., 80
- Nefedepine receptors, 136
- Nelp, Wil B., 113, 115, 143, 144
- Neonates, cardiac imaging, 174–175, 184, 186,  
188
- Neoplasia, *see* Cancer/neoplasia/oncology,  
diagnosis and treatment
- Neptunium, 8
- Neurochem Pharmaceuticals, 209
- Neurocirculatory asthenia, 55
- NeuroECAT scanner, 214
- Neuroscience, 122, 123, 124, 130, 131, 132, 136,  
137, 200, 201, 204, 205–209, 244  
chemical neurotransmission, discovery of,  
214  
discovery of neurotransmitters, 208–209  
early research, HNW, 44, 45  
early trainees specializing in, 146  
first scientific paper, HNW, 41–42

- Neuroscience (*cont.*)  
 genetic factors in neurodegenerative disorders, 242  
 Mind/Brain study program, 219–228  
 neurotransmitter function, 131  
 N-methyl spiperone (NMSP), C-11, 135, 211  
 PET sensitivity and specificity, 217  
 receptor studies, 205, 206
- Neutron activation analysis (NAA), 111, 112
- Newell, Robert, 71
- New England Nuclear Corporation, 141–142, 189
- Nickoloff, Ed, 134
- Nickoloff, Eileen, 116
- Nicotine, 131
- NIH, *see* National Institutes of Health (NIH)
- Nirenberg, Marshall, 13, 14
- Nishina, Yoshio, 89–90
- Nitrogen-13, 78, 151, 159, 207
- NMDA receptors, 217
- N-methyl spiperone (NMSP), C-11, 135, 211, 212
- N-methyl spiperone, C-11, 218
- Nobel Prize, 3, 5, 6, 8, 83, 126, 205, 206, 209, 210, 214, 221, 228  
 Curies and, 67  
 Fermi, Enrico, 5  
 Hevesy, Georg, 3, 68, 78  
 Lawrence, Ernest, 8  
 Nirenberg, Marshall, 13, 14
- Normal values, establishment of, 250
- North Korea, 99
- Norton, Jane Anne, 49
- Nuclear Chicago Corporation, 106, 152, 158, 165
- Nuclear Data Inc., 106
- Nuclear energy, 6–7, 10, 87
- Nuclear fallout, 88
- Nuclear Instrumentation and Chemistry in Medicine program, 119, 120
- Nuclear magnetic resonance (NMR), *see* Magnetic resonance imaging
- Nuclear medicine  
 Japan, 149  
 patient education, 94
- Nuclear Non-Proliferation Treaty, 99
- Nuclear physics, 2–8, 7
- Nuclear Pioneer award, 125
- Nuclear reactors, 5, 10, 82, 87
- Nuclear Regulatory Commission (NRC), 145
- Nuclear stethoscope, 190, 191, 192, 193
- Nuclear testing, 88, 156
- Nuclear weapons, 10, 43, 90, 98
- Nursing, 124–125
- O**
- Oak Ridge Institute of Nuclear Studies, 77, 149
- Oak Ridge National Laboratory, 79
- Occupational radiation exposure, 145
- Ochi, Professor, 114
- Oeff, Karl, 251
- Ohio Nuclear scanner, 121
- Ohio State University, 125, 151, 156, 165
- Ojemann, George, 130
- O’Keefe, Sharon O., 124
- Oncogenes, 200
- Oncology, *see* Cancer/neoplasia/oncology, diagnosis and treatment
- Ontological approach to diseases, 55
- Operation Crossroads, 88
- Operation Ranger, 88
- Operation Troll, 90
- Opioid receptor studies, 122, 123, 124, 130, 136, 137, 206, 211, 215–217, 218
- Oppenheimer, Robert, 5, 81, 245
- Optical imaging, 247
- Ord, W.M., 162
- Organic chemists, 121
- Organizational issues, 248
- Organizational meetings, world congresses, 76, 148
- Orientation course, National Institutes of Health (NIH), 56
- Ortec, EG & G, 214
- Orthiodohippurate, I-131, 158
- Orthostatic hypotension, 55
- Osaka University, Japan, 114
- Osman, Medat Mohammed, 85
- Osmolality studies, 54–55
- O’Tauma, Lorcan, 145
- Overman, R.T., 77, 149
- Owens, 136
- Oxygen-15, 78, 129, 151, 207
- Oxygen metabolism, cerebral, 218
- P**
- Paget disease, 203
- Pain conditions, 130, 216
- Pakistan, 98–99

- Palmer, John, 247
- Pancreatic scans, 108  
  development of products for, 141  
  imaging procedures used at Johns Hopkins in 1964, 111
- Paneth, Fritz, 2, 68
- Paracelsus, 162
- Parametric images, 185
- Parkinson's disease, 123, 124, 129, 130, 204, 210, 213, 216, 218, 242, 244
- Parry, C.H., 162
- Particulates  
  airway clearance, 103  
  colloidal, 119, 126  
  lung scans, early studies, 126
- Patents, annihilation detection system, 124
- Pathology, 70–71
- Patient care, revenue generation, 54
- Patient education, 94
- Patient selection, cardiac imaging, 181
- Pediatric cardiology, 174–175, 184, 186, 188
- Peer review policy, 53–54
- Peptide neurotransmitters, 205, 209
- Perfusion defects, pulmonary embolism and, 172–173
- Perfusion lung scans, *see* Lung scans
- Pericardial effusion imaging, 111, 120, 121, 138, 183
- Peter Bent Brigham Hospital, 143
- PET scans, 127
- Pfizer, 42–43, 200
- Phagocytosis, 117, 167, 198
- Pharmaceutical industry, 145, 246  
  neurochemistry, Alzheimer's disease and amyloid studies, 209–210  
  regulatory issues, 247, 248
- Pharmacologists, 121
- Pharmacology/drug studies, 246, 250  
  brain scans/neurochemistry, 205, 206–209, 218  
  dopamine receptors, 210–211  
  drug design and development, 218–219  
  psychoactive drugs, 213  
  cancer drug design and development, 200  
  cardiac imaging, 193  
  early research, HNW, 43, 44  
  Mind/Brain program, 222  
  Radioactive Drug Search Committee (RDRC), 145  
  traditional Chinese herbal medicines, 193, 194, 195
- Phelps, Michael, 127, 208
- Phencyclidine (PCP), 217
- Phenotype, 227, 228, 238
- Phenotypic markers, 243
- Phosphonate, Tc-99m, 199
- Phosphorus-32, 2, 8, 9, 78, 126, 151  
  first use of, 244  
  Yamashita group, early studies, 77
- Phosphorus isotopes, early leukemia treatments, 69
- Photographic plates, 65, 68
- Photonics, 226
- Physical chemist, 120
- Physical examination, role in medicine, 48
- Physicians, 134
- Physicists, 134
- Physiological approach to disease, 54–55
- Physiological studies  
  early tracer experiments, 69  
  grant applications for development of, 121
- Piezoelectric detection, 65, 68
- Pilots, pulmonary blood flow studies, 102
- Pipberger, Hubert, 177
- Pitchblende, 65, 68
- Pitressin, 55
- Pitt-Rivers (thyroid studies), 162
- Pituitary ADH, 54–55
- Placenta, 111
- Plants, tracer studies, 68
- Plasma protein-bound iodine, 112
- Pleotropism, 227
- Pliny the Elder, 161
- Plutonium-239, 8, 9
- Polonium, 68, 69
- Positron camera, brain scans, 208
- Positron emission tomography (PET), 75, 77, 78, 129, 130, 136, 149, 196–197, 236–237  
  brain scans, 207, 209; *see also* Brain scans  
  Alzheimer's disease and amyloid studies, 209–210  
  brain chemistry and behavior, 206  
  C-11 NMSP imaging, 211  
  drug design and development, 218–219  
  opiate receptor studies, 216  
  sensitivity and specificity, 217  
  cancer detection, 203, 204

- Positron emission tomography (PET) (*cont.*)
- cardiac surgery patient selection, 181
  - in China, 196
  - clinical acceptance of, 133
  - clinical applications, 130
  - computer applications, 178
  - development of, 127
  - early developments, 109
  - early trainees specializing in, 146
  - efficiency and throughput issues, 246
  - facility dedication, 135–136
  - first model, 60
  - funding of early programs, 122, 213–214
  - hybrid imaging, 13, 248; *see also* Anatomical imaging
    - infectious disease applications, 230
    - Johns Hopkins University facilities, 131
    - Mind/Brain program, 219–228
    - normal values, establishment of, 250
    - spatial resolution increases, 247
- Positron emitters, 125, 156
- brain scans, 107
  - factors affecting utility, 126
- Post-doctoral trainees, 135
- Potassium-38, 156
- Potassium-42, 105, 184
- Potassium-43, 184–185
- cardiac imaging, 188–189
  - myocardial blood flow studies, 105
  - myocardial infarction, 185
- Potchen, James, 117
- Practical threshold for exposure, 97
- Price, Julie, 123
- Principal investigators, 54
- Principles of Experimental Medicine* (Bernard), 64
- Principles of Nuclear Medicine*, 143
- Production capacity, current status, 246
- Professorship
- appointment to, 126, 128
  - Henry W. Wagner Jr. Professorship in Nuclear Medicine, 140, 221
- Prokhorov, A.M.M., 223
- Protein-bound iodine, 112
- Psychiatry, 146, 205, 209
- dopamine receptors, 210–211, 214, 218
  - opiate receptor studies, 216
  - psychoactive drugs, 213
- Publications
- cardiac imaging, 193
  - first scientific paper, HNW, 41–42
  - Medical Radioisotope Scanning (1960), 110–111
  - Principles of Nuclear Medicine* (1968), 143
- Public opinion/public relations, 90, 92–94
- Pulmonary blood flow/pulmonary embolism, 102, 111, 168–171
- clinical acceptance of lung scans, 170–171
  - computer analysis, 179
  - early studies and presentations, 99, 100, 101
  - embolectomy, 171
  - experimental models, 168–170
  - perfusion defects, 172–173, 174
  - xenon-133 studies, 171
- Pulmonary function studies, ciliary clearance, 103
- Pulmonary hypertension, 172
- Pulmonary scans, *see* Lung scans
- Pyramine, 132
- Pyrophosphate, Tc-99m, 199
- Q**
- Quality issues, 246
- Quantitative autoradiography, 201
- Quinn, James, 175
- R**
- Radar, 6, 8, 9
- Radiation dispersal devices (RDD), 98
- Radioactive Drug Search Committee (RDRC), 145
- Radioactivity, discovery of, 65–68
- Radiobiology, 143
- Radioimmunoassay, 85, 135, 205, 209, 217
- Radioiodine scans, *see* Iodine scans
- Radioisotope scanning
- defined, 111, 137
  - invention of, 162
- Radiology, 14, 70–71, 78
- Radionuclide generator/radioisotope cow, *see* Generators/radioisotope cow
- Radiotracer IND, 219
- Radium, 68, 69
- Radon, 2, 3, 92, 98
- Rare earth element mining, 94–95
- Rasool, Misbah Masood, 123
- Razzak, Mohammed A., 113
- Reactor development, 82
- Reba, Richard, 143, 144, 155

- Receptor binding studies, 122, 123, 205, 206  
Recombinant DNA, 107  
Records, health, 249–250  
Rectilinear scanners, *see* Scanners  
Red blood cells, 79, 244  
    angiocardiography, 186, 188  
    rectilinear scanner studies, 117, 118  
    spleen scanning, 118–119  
    T3 uptake test, 111  
Regional biochemistry, 126  
Regulation, federal, 79  
Regulation and control, 79–82, 92  
    drug design and development, 200, 218–219  
    gray areas, 247–248  
    Radioactive Drug Search Committee (RDRC) formation, 145  
Reivich, M., 207  
Renda, Fevzi, 85  
Research, 129  
    DOE sponsorship, 87  
    drug design and development, 218–219  
    funding, 82  
    peer review policy, 53  
    training programs, 135  
    U.S. government support, 11, 81–82  
Research and development needs, 246  
Reserpine, 208, 213  
Residency programs, nuclear medicine, 119, 180  
Residency training, HNW, 11, 12–13, 47–49, 50–51  
Resource sharing, 197  
Restriction enzymes, 107  
Reticuloendothelial system, 59, 75, 117, 119, 167–168  
Revenue generation, patient care as source of, 54  
Rhenium-186, 123  
Rich, Adrienne, 46–47  
Rich, Arnold, 46–47  
Richards, Powell, 58, 59, 128, 164  
Richter, Curt, 39, 40, 42, 44, 46, 54, 56, 222, 228  
Risk-benefits approach to radiation, 92  
Risk perception, 99, 124  
RNA, 13  
Roentgen, Conrad, 65  
Roosevelt, Franklin, 5  
Rose Bengal, I-131, 110, 111, 117  
Ross, Joseph, 232  
Ross, Richard, 135, 197  
Rubidium-81, 184  
Rubidium-81/krypton-81m, 208  
Rusheng, Cai, 195  
Ruth, Thomas, 130  
Rutherford, 68  
Ryan, John, 76, 148  
  
S  
Sabiston, David, 75, 168, 170  
Sachariah, George, 134  
Safety, radiation, 94, 98  
Safety and effectiveness assessment, 180  
Salvatore, Marco, 75  
Sasaki, Yasuhiro, 112, 113, 144, 159  
Satellite operations, nuclear medicine in surgical ICU, 145  
Saudi Arabia, 123  
Savannah River National Laboratory, 87  
Scandatronix cyclotron, 136  
Scanners  
    cameras versus, 104  
    grant applications for development of, 121–122  
    rectilinear, 61  
        brain scans, 207  
        cardiac imaging, 183  
        early models, 107, 108, 117–118  
        invention of, 162, 163, 164  
        iodine-131 brain imaging, 63  
        thyroid scans, 161, 162–163, 163–164  
SCH 23390, 132  
Schally, Andrew V., 205, 209  
Scheffel, Ursula, 251  
Schizophrenia, 124, 130, 146, 205, 209, 210, 211  
    early research, HNW, 44  
    glutamate receptors, 217  
School, 24, 25, 26, 27, 28, 32–38  
Schwaiger, Marcus, 151  
Scintillation camera, *see* Camera, scintillation  
Scintillation detector, 119  
    presentation to Japan, 1954, 90  
    thyroid scans, 162–163  
Scopolamine, 44  
Screening, cardiological, 138–139  
Seaborg, Glenn, 5, 8, 58, 81, 83, 126, 144, 162, 183, 244, 245  
Second law of thermodynamics, 55, 125  
Seeds, Asa, 80  
Segre, Emilio, 58, 183  
Selenium-75, 111, 198

- Selenomethionine, S-75, 108, 198
- Serotonin receptor studies, 124, 136, 137, 208–209, 218
- Seta, H., 150
- Shanghai, 195
- Shannon, James, 13, 14, 52, 53
- Sharp (pulmonary embolectomy), 171
- Shulman, Lawrence, 13, 119
- Shunting, 174, 175, 181, 184, 188, 189
- Sigma receptors, 218
- SIMIS system, 106
- Single photon emission computed tomography, *see* SPECT (single photon emission computed tomography)
- Single photon emitters, 126, 208
- Smith, Beatrice, 155
- Smith, Ed, 112
- Smith, Hamilton, 107
- Smith, James, 155
- Snyder, Solomon, 136, 206, 210, 215, 216
- Society of Nuclear Imaging in Drug Design and Development (SNIDD), 134
- Society of Nuclear Medicine, 70, 76, 80, 84, 125, 129, 140, 148, 151, 245
- computers, early developments, 107
  - Nuclear Pioneer award, 125
  - Oenology Society, 116
  - office holders, 143–144
- Soffer, Alfred, 171
- Software, 177, 195
- Soil tracer studies, 68
- Sokoloff, Louis, 201, 207, 208
- Soley, Mayo, 244
- Somatostatin, 123, 205, 209
- Sommer, Alfred, 42
- Sostre, Samuel, 145
- Soufer, Robert, 130
- South Korea, World Congress, 2006, 76
- Soviet Union, 80, 82, 88, 226, 227
- Chernobyl, 92, 93, 94, 97
  - Cold War, 10, 14, 44, 90, 98
- Specialization issues, nuclear medicine, 70–71, 120, 139, 247
- SPECT (single photon emission computed tomography), 77, 78, 130, 149, 236
- brain scans
    - Alzheimer's disease and amyloid studies, 209–210
    - brain chemistry and behavior, 206
    - opiate receptor studies, 216
  - cancer detection, 204
  - cardiac imaging, 188
  - cardiac surgery patient selection, 181
  - hybrid imaging, 13, 248; *see also* Anatomical imaging
    - spatial resolution increases, 247
- Spectrograph, large-scale, 164
- Spectrometers, gamma ray, 119
- Spectrophotometry, 210
- Sperry Gyroscope Company, 8
- Spiroperidol, 122, 130
- Spleen scans, 111
- colloidal particles, 119
  - early clinical uses, 118–119
  - early publications, 120
  - rectilinear scanner studies, 117
  - technetium-99m, 59, 61
- Sputnik, 58
- Stang, Louis, 58, 128, 164
- Stanley, T., 124
- Steady state conditions, physiological, 55
- Steatorrhea, 113
- Stethoscope, nuclear, 190, 191, 192, 193–196
- Stetten, Dewitt, 13, 119
- St. Martin's Camp, 22–24
- St. Martin's schools, 25, 27
- Stoltz, Kate, 124
- Strassman, Fritz, 5, 6
- Strauss, William, 116, 143, 144, 185, 188
- Stroke, 136
- Strontium-85, 203
- Strontium-87m, 83, 143, 156, 203
- Subramanian, Kaliyani, 183
- Subramanian, Manny, 59, 144, 183
- Sulfur-75 selenomethionine, 108
- Sulfur colloid, cancer detection, 199
- Summer camp, 22–24
- Surgical follow-up, cardiac imaging, 185
- Surgical ICU, 145
- Suriclone, 132, 218
- Suzuki, Shinzo, 88
- Sydenham, Thomas, 237
- Sympathetic nervous system, 45
- Synthesis, chemical, 121
- Szilard, Leo, 5, 7, 8, 81
- T**
- Tamminga, Carol, 146
- Tanman, Mahmet Ali, 85
- Taplin, George, 61, 167, 168



- Tardive dyskinesia, 130  
Tauxe, Dub, 232  
Taxonomy, molecular, 240  
Team work, research, 54  
Technetium-99 and 99m, 12, 58–61, 64, 141, 208  
    Anger camera and, 158  
    brain scans, 207  
    cancer detection, 199, 203  
    cardiac imaging, 182, 183, 184, 187, 189–190, 191, 192  
        angiocardiology, 186, 188  
        motion picture display, 185  
        ventricular motion studies, 105  
    colloidal particles, 119  
    computer analysis, 179  
    dosage requirements for detection, 165  
    generation of (radioisotope cow), 58, 126, 164, 193  
    immune system and infectious disease studies, 229, 230  
    properties of single-photon emitters, 126  
    regulatory issues, 145  
    thyroid, 160  
    trainees, 123  
Technetium-99m pertechnetate, 61  
Technetium isotopes, 58  
Technical support, 108, 120, 124  
Technology transfer, 84  
Teller, Edward, 58  
Tellurium-132, 58, 126, 164  
Tenorio, Luis E.M., 144  
TerPogossian, Michel, 126, 127, 129, 136, 208  
Terrorism, 10, 98  
Thallium-199, 188  
Thallium-201  
    cardiac imaging, 187, 189–190  
        myocardial blood flow studies, 105  
        normal distribution, 186  
    PET scans and, 130  
Therapeutic applications, 244  
    cancer treatment, 68, 126, 165; *see also*  
        Cancer/neoplasia/oncology, diagnosis and treatment  
    early developments, 69  
    early tracer experiments, 69  
    early trainees specializing in, 143  
    genetic technology, 242  
    grant applications for development of, 121  
    Japanese studies, 149  
        pharmaceutical industry and, 145  
        regulatory issues, 247  
        training requirements, 78  
Thermodynamics, second law, 55, 125  
Thomas, Vivian, 168–169  
Thorium, 68, 69, 94–95  
Thornon, Alma, 16  
Thornton, Jim, 16  
Three M (MMM), 76, 148  
Three Mile Island accident, 92, 98  
Thresholds, practical, 97  
Thromboembolism, cerebral, 208  
Thrombolytic therapy, 172–173, 174, 179  
Thyroid studies, 5, 12, 58, 244, 245  
    cancer detection, 203  
    computer analysis, 179  
    discovery, development, diseases, 160–166  
    early developments, 69–70  
    early trainees, 143  
    exposure studies, Bethesda training course, 112  
    imaging procedures used at Johns Hopkins in 1964, 111  
    radioiodine scans, 63  
    rectilinear scanner studies, 117  
    technetium-99m imaging, 59, 61–62, 64  
Thyroxine (T<sub>4</sub>), 162, 208  
Thyroxine binding protein, 111  
Tiaspirone, 200  
Tissue analysis, 111  
Tizard, Henry, 6  
Tobias, Cornelius, 156  
Todd, James S., 233  
Tokyo University, 77  
Tomaki, 114  
Tominaga, Mr., 159  
Tomography, 109, 133  
Torizuka, Professor, 159  
Totter, John, 128  
Touya, Eduardo, 145  
Touya, Juan, 145  
Tow, Donald, 144  
Toxicology, 145  
Trace element analysis, 111  
Tracer principle, 2, 3, 4, 12, 16, 68, 69, 78, 247  
Traditional Chinese medicines, 193, 194, 195  
Trainees and mentors, 77, 85, 86, 116, 142–146  
    Chinese, 196  
    Indian, 123  
    Japanese, 112, 113, 114, 115, 146, 185, 186

- Trainees and mentors (*cont.*)  
   post-doctoral, JHU, 135  
 Training programs and courses, nuclear  
   medicine, 112, 113, 123, 140, 196  
   author attendance, 112  
   certification, 71  
   certifying board, 180  
   Colby College, Maine, 116  
   early recommendations, 70  
   grants, 135  
   Johns Hopkins University, 112, 113, 114, 115,  
     116  
   Naval Medical Center, Bethesda, 112  
   Ohio State University, 156  
   video system for cardiology training at JHU,  
     195  
 Treatment IND, 219  
 Trendelenberg operation, 171  
 Triiodothyronine (T3), 69–70, 111, 162  
 Tritium, 126  
 Tsan, Min-Fu, 134  
 Tuberculosis, 103, 144, 145, 172, 204, 230, 231  
 Tung, C.L., 195  
 Turkey, 85, 123  
 Tuve, Merle, 128  
 Tuxedo Park, 7, 8  
 Tydings, Joseph, 91
- U**  
 Udenfriend, Sidney, 52, 210  
 Ueda, Hideo, 71, 77, 146, 148, 149  
 Union Carbide Nuclear Company, 141  
 United Nations, 79, 81, 84–85  
 United States Coast Guard Academy, 36, 37  
 United States Department of Energy, 10, 11,  
   87–88, 145  
   Human Genome Project, 107  
   regulatory issues, 248  
 United States Food and Drug Administration,  
   247–248  
 United States government policy, 10, 11  
 United States Naval Medical Center, Bethesda,  
   112  
 United States Public Health Service, 135  
 United States Veterans Administration, 130  
 University nuclear reactors, 10  
 University of California, Berkeley, 9–10, 78–79,  
   82, 83, 244  
 University of California, Los Angeles, 133  
 University of California, San Diego, 10
- University of Chicago, 164  
 University of Michigan, 133  
 University of Oregon, 142  
 University of Pennsylvania, 109, 133  
 University of Washington, Seattle, 113, 115,  
   142  
 Uranium, 65, 68, 69, 164  
   global stores/supplies, current, 99  
   monozoite, 94–95  
 Uranium-235, 9, 10  
 Uranium-239, 8  
 Urokinase therapy, 172–173, 174, 179
- V**  
 Valve disease, 181, 189  
 Van Heerden, Ben, 141, 144  
 Van Heerden, Phillip, 141  
 Varian, Russell, 8  
 Varian, Sigurd, 8  
 Varma, Vijay, 129  
 Vascular system, imaging procedures used at  
   Johns Hopkins in 1964, 111  
 Vassake (thyroid disease), 161  
 Veall, Norman, 64, 208  
 Ventriculography/ventricular function, *see*  
   Cardiology, nuclear  
 Vietnam War, 90  
 Virology, 230  
 Vitamin B-12 analysis, 122–123  
 Von Neumann, John, 177
- W**  
 Wagner, Albert, 23, 30  
 Wagner, Alma, 16  
 Wagner, Anne Barrett, 14, 15, 41–42, 56, 73,  
   128, 129, 144, 146, 156, 252  
 Wagner, Barbara Krautblatter, 16–18, 33  
 Wagner, Elizabeth, 57  
 Wagner, Gertrude, mother of HNW, 16, 20, 24,  
   29  
 Wagner, Gertrude, sister of HNW, 20, 30  
 Wagner, Henry N. Jr., 59, 73, 74, 75, 131, 143  
   Baltimore home and neighborhood, 19–22,  
   29, 31  
   courtship and marriage, 41–42  
   early years, 18–19  
   first publication, 41–42  
   graduation from medical school, 45  
   grandparents, 16–18  
   medical school, 40–41

- parents, 24, 25, 26
  - parish priests, 22
  - research, undergraduate and graduate, 39–41
  - residency of, 11, 12–13, 46–47, 50–51
  - ROTC training, 37
  - scholarship, 41
  - school, 24, 25, 26, 27, 28, 32–38
  - summer camp, 22–24
  - undergraduate education at JHU, 35–36, 37, 38
    - United States Coast Guard Academy, 36, 37
  - Wagner, Henry N. Sr., 16, 17, 29, 32, 52
  - Wagner, Herman, 20, 22, 23, 24, 30
  - Wagner, Nick, 49, 50
  - Wahl, Richard, 139, 140, 221
  - Walton, John, 14
  - Warburg, Otto, 203
  - Washington University, 5, 10, 85, 127, 129
  - Waste disposal issues, 87, 92, 94–97, 112
  - Watson, James, 80, 107
  - Watson-Watt, Robert, 8
  - Waud, John, 134
  - Weapons proliferation, 98–99
  - Weis, Arthur, 142
  - Weisfeldt, Myron, 136, 197
  - Weiss, Sue, 116
  - Welch, Michael, 154
  - WFNMB, foundation of, 73
  - White blood cell labeling, 230
  - Whitehead, A.N., 137
  - Wieseltier, Leon, 98
  - Williams, Frank, 42
  - Williams, Robert, 91
  - Woking Maternity Hospital, 57–58
  - Wolf, Alfred, 109, 128, 207
  - Wolf, Walter, 153
  - Wong, Dean, 122, 134, 145, 212
  - Wood, Barry, 85
  - Woods, James W., 44
  - Woodward, Ted, 50
  - World Congresses and meetings, 71, 73, 75–76, 146–148
  - World War II, 9, 32–33, 35–36
  - Worley, Paul, 141
  - Wu Ying Kai, 195
- X**
- Xenon-122, 126
  - Xenon-133, 141, 185
    - brain scans, 208
    - lung scans, 171, 175
  - X-ray film, 65
  - X-rays, discovery of, 65
- Y**
- Yalow, Rosalyn, 76, 147, 205, 206, 209
  - Yamashita, H., 77, 149
  - Yonekura, Yoshiharu, 144
  - Young, Frank E., 219
  - Young, John, 15
  - Young Turks, 52–53
  - Yttrium, 94
  - Yttrium-87, 203
- Z**
- Zadje, Charles, 106
  - Zerhouni, Elias, 1, 2, 139
  - Zero gravity studies, 102
  - Zero threshold hypothesis, 92, 97
  - Zevalin, 204
  - Zuidema, George, 145