Epilogue

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 Univesity 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.

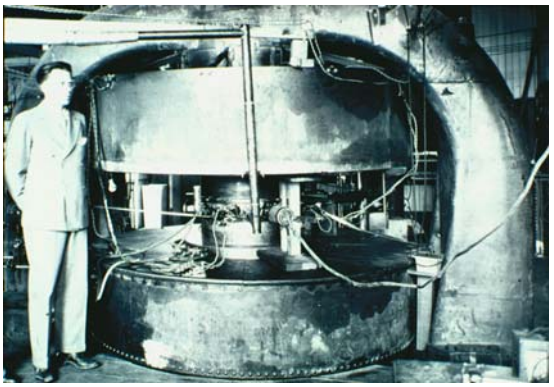

Figure 185 Ernest Lawrence, inventor of the cyclotron.

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 histopathogy.

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 "hydrid" 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 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