

Health Care and Nuclear Medicine in France

A Conversation Between Dominique Le Guludec, Johannes Czernin, and Jérémie Calais

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Johannes Czernin, editor in chief of *The Journal of Nuclear Medicine*, and Jérémie Calais, associate editor, talked with Dominique Le Guludec, president of the Haute Autorité de Santé (HAS; French High Authority of Health). In this position, appointed by the president of the Republic of France, she chairs the HAS scientific deliberative board and is responsible for overseeing the institution's strategic planning and ensuring programming and implementation of various legislative assignments. Before her current appointment, Dr. Le Guludec headed the Nuclear Medicine Department (1993–2017) and Medical Imaging Unit (2006–2011) at the Bichat Hospital (Paris) and presided over the board of directors for the French National Institute of Radioprotection and Nuclear Safety (IRSN; 2013–2017).

After cardiology residency training early in her career, Dr. Le Guludec specialized in biophysics and nuclear medicine at the University Paris–Diderot teaching hospital, Bichat. Her research interests and training led her to manage Bichat's Department of Nuclear Medicine and Medical Imaging Unit as well as the INSERM (National Institute of Health and Medical Research) Research Cardiovascular Imaging Team, which was responsible for running several national and European innovation programs in molecular imaging and nanotechnology.

In addition to academic and medical practice roles, Dr. Le Guludec held various administrative roles throughout her career, including as president of the Medical Establishment Commission of University Hospitals Paris Nord. She also undertook scientific responsibilities at the international level as president of the Cardiovascular Committee of the European Association of Nuclear Medicine (EANM; 2002–2006), member of the European Council of Nuclear Cardiology (2005–2013), and member of the EANM Executive Committee (2011–2013). In September 2021 she was appointed vice president of the Heads of Agencies Group, which convenes 20 public health technology assessment bodies across Europe.

Dr. Calais: *It's a great honor to speak with you. When we saw each other the last time in 2016 you were the chair of the Department of Nuclear Medicine and Biophysics at the Bichat University Hospital in Paris. Since then, you've become president of the French HAS. We asked you to participate in this discussion because your career path from nuclear medicine to a national leadership position is inspiring. Can you tell us a bit about your career?*

Dr. Le Guludec: I did not start out as a nuclear medicine physician. I began as a clinical cardiologist. I maintained a weekly outpatient consultation for cardiac patients throughout my career until quite recently. At the time of my university fellowship and assistant professorship in cardiology, I did 2 years of research in the Department of Molecular Imaging at the Commissariat à l'Energie Atomique et aux Energies Alternatives Hospital in Orsay. I worked on various quantitative PET imaging approaches, including receptor imaging, which was very innovative at that time. This was the origin of my interest in nuclear medicine and molecular imaging. I subsequently started training in nuclear medicine and never regretted it. In the beginning I focused mostly on research and clinical nuclear cardiology but expanded my scope and eventually covered all aspects of diagnostic and therapeutic nuclear medicine. Finally, in 1988, I took a position in the Department of Nuclear Medicine and Biophysics at Bichat University Hospital, which at the time had only a single-detector γ -camera. This was a challenge, but, over time, we created a strong and robust program. When I left to become president of HAS in 2017, the nuclear medicine department of Bichat hospital had become a fairly large department, with 3 SPECT systems, 1 PET/CT, and 1 PET/MR in installation. I fought for expansion of equipment, space, and medical and non-medical staff to bring both the clinical department and research unit to a high level to match the quality of the university hospital.

Dr. Czernin: *In Europe, trainees and faculty need to combine research with clinical work. It's a little different in the United States, where research is often conducted by people with limited clinical responsibilities, so that they have time for research. What about the life/work balance, as they call it now? How can young MDs do high-level research and provide excellent clinical service at the same time?*

Dr. Le Guludec: In France, we have 2 categories of doctors: those who have a university position and conduct research, teaching, and clinical activities; and others, who are focused on the clinic and are not expected to do academic research. In my group, we decided that it was good for everyone to do both clinical work and research—but this could be clinical, applied, or preclinical research. Depending on individual preferences, they could do more or less clinical or fundamental research.



Dominique Le Guludec, MD, PhD

Dr. Czernin: *What does the clinical service look like?*

Dr. Le Guludec: Some physicians provide only nuclear medicine services, whereas others focus on nuclear cardiology, oncology, or endocrinology. But there is a lot of collaboration, a strong team spirit, and constant communication and exchanges about patient cases. Although individuals have specific interests, everyone is involved in everything.

Dr. Calais: *One of your main career achievements is that you built a successful academic and clinical department. What about all the other responsibilities you took on, like at the National University Council or the IRSN. How did this happen?*

Dr. Le Guludec: I never looked for these functions; they were the results of unplanned opportunities. Maybe women do less career planning than men—I never planned anything. When some of my professional attempts were successful, I was asked to do more. I was on the faculty board for my university and was the only woman in that group for a long time. I had major responsibilities for the medical commission of a group of 7 big hospitals in Paris. I was asked to serve as the chair of the board of directors of the IRSN in 2013, when the former chair became president of HAS. She then became the Minister of Health and proposed my name to the French government to take over at HAS. This has become the most challenging assignment I've ever taken on. It's full-time (actually full-time \times 3!). Why did I choose to move? I gave it quite a lot of thought before jumping into this new challenge. First, nuclear medicine gave me a very broad view of medicine, which is good for what is expected at HAS. In addition, as I approached the end of my university career, it was time to let my successor take the department lead at the

must cover all nuclear medicine content and, of course, radiation protection and biophysics, as well as other related clinical fields.

Dr. Czernin: *Are you specifically training residents for research?*

Dr. Le Guludec: When residents and fellows joined my department, I asked them to work toward a master of science degree, because even for clinical nuclear medicine training, basic science knowledge is very important. They also had to learn how to read and write scientific papers and how to ask the right questions. All residents at Bichat have done master of science degrees, and some have gone on to complete PhDs.

Dr. Calais: *Including some research methodology in the training curriculum will benefit nuclear medicine as a whole. At UCLA, I had the opportunity to participate in the translation of prostate-specific membrane antigen-targeted radiopharmaceuticals from research into clinical care. By interacting with the regulatory institutions, the Food and Drug Administration, insurance companies, Medicare, and the guideline committees, we learned what was required and the kinds of evidence needed for regulatory approval and reimbursement. The large volume of data available in PubMed from what were mostly retrospective studies was not helpful in meeting the evidence criteria. What is your position and that of HAS on evidence generation?*

Dr. Le Guludec: Nuclear medicine is often coming in with small, not very well-designed studies while competing with very strong specialties and industry. A product such as a radio-nuclide agent for therapy is competing with big pharma and with very expensive drugs. Clinical research has to be much

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hospital. Finally, it was the last opportunity in my life to change my career completely.

Dr. Calais: *Driven by research interests, you made a choice to move from cardiology to nuclear medicine. Do you think you would have grown the same way if you had stayed in cardiology? In nuclear medicine you gained a very specific expertise.*

Dr. Le Guludec: I never thought about it in that way. On the contrary, I have the feeling that nuclear medicine is very broad in its applications. Some cardiologists are focused on cardiology and only cardiology. But when you do nuclear medicine you have to deal with oncology, infections, cardiology, neurology, etc. It gives you a very broad overview of medicine.

Dr. Czernin: *Can we talk about your view of nuclear medicine residency programs and the differences between the standing of nuclear medicine in Europe and the United States? What is the curriculum in France, how long is the training, and what are the priorities?*

Dr. Le Guludec: Training has changed a lot. When I started in the 1980s, it was possible to train in 2 specialties simultaneously. Today physicians have to choose a specialty at the beginning of residency, just after medical school. It's a pity, because nuclear medicine could be seeded by various specialties and provide opportunities for cardiologists, oncologists, endocrinologists. This would enrich the field. Today 4 years of training are required in which, theoretically, the trainee

stronger and better structured to be competitive. At HAS, we are evaluating many new and very innovative drugs. Nuclear medicine has a strong place, but we have to demonstrate that properly.

Dr. Czernin: *You talked about the different subsections of nuclear medicine that you integrate. Can you comment on the current development of theranostics in academic departments as well as in clinical practice? How available are the new theranostic approaches in France?*

Dr. Le Guludec: For a long time, nuclear medicine developed approaches mostly for imaging and subsequent treatment of neuroendocrine tumors and, more recently, prostate cancer. The HAS has to evaluate and validate all products for reimbursement. Often the nuclear medicine data are weak in proving superiority over other treatments. The field of nuclear medicine and theranostics must do a much better job in coming up with high-quality evidence to support therapeutic or diagnostic tools.

Dr. Calais: *In your view, who is going to do theranostics? Who does the treatments? Medical oncologists, radiation oncologists, or nuclear medicine physicians? In the United States, it's much more open than in France. How important is the independence of nuclear medicine? In the United States, it's actually usually a division of radiology. How important is independence within increasingly integrated health-care systems?*

Dr. Le Guludec: Nuclear medicine has a very specific knowledge base and very specific competence. Whereas 90% of radiology is still very anatomic, nuclear medicine now has a functional and mostly molecular approach. It's impossible not to collaborate, so we have to be open. We should not be afraid to be eaten because we are small. We have a very specific expertise, and no one can do it in our place. So, in my view, there is no risk. The risk for us is in not being able to prove our added value sufficiently.

Dr. Czernin: *Let's talk about HAS for a moment. The agency is dealing with an enormous variety of regulatory and legislative issues that range from being responsible for all measures taken against coronavirus disease 2019 (COVID-19), to device approvals, to drug approvals, to training issues, to physician competence, and more. Can you describe the main roles of this agency?*

Dr. Le Guludec: We are not a government agency. I am nominated by the president of France, after approval by the equivalents of the Congress and Senate, but HAS is an authority that is independent of political decisions. It is a scientific agency that advises the government, which can take or leave the advice. Mostly they accept the advice. Why? Because we develop recommendations based on science and consensus, we gain legitimacy. But this notion of independence from politics and from the industry lobby is important: we have very strict rules about conflicts of interest for our experts, for all of us. This is critically important in the eyes of our citizens.

We have 3 big tasks aimed at improving quality in the health system: to assess and appraise all medical products and devices and procedures; to make all recommendations for good practice for professionals and establish all guidelines for diseases and for public health, including prevention and screening (e.g., we are currently working on lung cancer screening guidelines); and to measure and improve quality in hospitals, clinics, private practice, social, medical/social, elder care, and so on.

These are separate departments, but it gives us quite a complete view of the health system. For instance, all health institutions (private or public) must be certified by HAS. The public system pays for these certifications at no cost to the institutions.

Dr. Calais: *You told us that your annual budget is €60 million, but given the enormous tasks to be completed by your 440 coworkers, is this sufficient?*

Dr. Le Guludec: We work with many external experts. Working groups include 1 or 2 people from HAS, but the members are external experts. So, HAS provides the structure, but we work with many more people. We have thousands of experts working with us.

Dr. Czernin: *There is a misconception in America about European health-care systems, which are often called socialist. I wanted to go into some of the specific differences between these systems. What are the priorities of the French system? You mentioned one already: disease prevention and overall health.*

Dr. Le Guludec: We are very committed here to equity. All people must have equal access to care, which is considered a human right. Much effort is put into delivering the same quality of care and access to health care for everyone in France. This is not easy, because, as in the United States, there are parts of the country where doctors don't want to go to. We also have a shortage of doctors, nurses, and technicians.

Dr. Czernin: *Physicians make much more money if they work for private entities. Is the health care provided by private practice also available for everyone, or do patients have to have additional private insurance to cover the costs?*

Dr. Le Guludec: In France, out-of-pocket payments account for 8% of all health spending. So, it is very little. These out-of-pocket costs are related to specific domains—dental and so on—that are not so well reimbursed. The great majority of health care is reimbursed either by national or private insurance.

Dr. Czernin: *In the United States, out-of-pocket contributions accounted for 12% in 2018—double the percentage in France. Overall U.S. health-care expenditure was around \$3.8 trillion in 2018, meaning that out-of-pocket payments accounted for close to \$400 billion. That's an enormous stress for many patients. In which direction is France moving? Is it set in stone that the system will remain focused on equity, or is it trending more toward for-profit?*

Dr. Le Guludec: French people are very attached to their public health care as it is now. We have presidential elections next year, and none of the candidates plan to touch the public system of health care. It's written in our DNA. The French health-care system is beautiful but, of course, with many imperfections. Yet, if you ask French citizens, they are not ready to move to private. They prefer to pay more taxes for health but to keep this system.

Dr. Czernin: *There must be something good about the French system, because I compared the life expectancy data for France and the United States. The French live 7 years longer.*

Dr. Le Guludec: There are many differences in the way we live—in the way we eat, for example. The health system is not the only determinant of life expectancy. It is one of the components but not the only one.

Dr. Czernin: *We have minorities and large immigrant populations, as well as poverty. We have large groups of patients who are underserved. France also has immigrants. How is health care covered for immigrants?*

Dr. Le Guludec: There is a solidarity fund that covers health care for all. If immigrants are living in France and are paid in France, they get health care like everybody else. Illegal immigrants have limited access. If they go to the hospital, they will be treated but will not receive screening or preventive health care.

Dr. Calais: *We are also interested to know how COVID-19 has affected your work.*

Dr. Le Guludec: It has been quite tricky. We have a fairly robust way of working. We apply scientific rigor, transparency, independence, and are a “consensus machine.” But this process takes time. With COVID-19, we had to move toward very quick evaluations, which raised the level of uncertainty. That's not so easy for the teams here, but they did very well. I think we helped as much as we could in this crisis, and we are still doing that.

Dr. Calais: *You emphasized the time that it takes to analyze and achieve consensus. Misconceptions and mistrust are high among the general population about recommendations coming from the government. One of the reasons is that people believe that we, as experts, should know everything. We need to communicate transparently about those things that we don't know. False statements induce so much long-term damage. What does COVID-19 teach us about the perception of science, which has been degraded in the public*

estimation and where one can say anything, whether it's true or not? What can be done to restore trust?

Dr. Le Guludec: We recently held a very large symposium about scientific expertise in crisis. This is an important discussion. We don't communicate enough; we must be very transparent during this crisis. We did a lot of work with journalists, because they were completely lost. We were speaking one day about viral testing and the next day about serologic testing, and this created confusion. So, we had many sessions to explain these and other topics: What is a diagnostic test? What information do we get from serum tests? Why is this test better than another? I believe that HAS has not been contested in its evaluations in this crisis. Of course, we have the conspiracy theorists and antivaccine groups who don't hear anything. But the large majority of the population had confidence in what we were telling them.

Dr. Calais: *We are coming to the end of this discussion. Let me return to nuclear medicine. As a national health-care leader in France, what is your view on the future of nuclear medicine and theranostics?*

Dr. Le Guludec: I am very optimistic about the future of nuclear medicine. Its potential is enormous. Nuclear medicine has to rethink its evaluation processes and provide evidence that its innovations change outcomes. The competition is tough. The field has to understand and apply the rules of clinical product development for therapy and also for imaging. HAS is currently changing the process in France to have medical imaging in general reviewed by a new group dedicated to diagnostic products rather than by the same group that evaluates therapeutics. So, we are proposing a new way to evaluate all diagnostic procedures. We will have to put that into law, which is a fight in which I hope to succeed before the end of my mission here.

Dr. Calais: *That's great to hear. This would be of great benefit to nuclear medicine. Do you have a final message for young people in our field?*

Dr. Le Guludec: Nuclear medicine and health care are great fields to be pursued with great passion. I have never been bored one day in my life.

Dr. Calais: *That is the best message. We thank you very much for providing us and our readers with your insights into nuclear medicine and global health-care issues.*