

# Leadership in Patient Advocacy

## A Conversation Between Josh Mailman and Thomas Hope

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**T**homas Hope, an associate professor in the Department of Radiology and Biomedical Imaging at the University of California, San Francisco, spoke with Josh Mailman, an internationally recognized advocate for neuroendocrine tumor patients as well as an advocate for nuclear medicine and molecular imaging. Mr. Mailman is the inaugural chair of the SNMMI Patient Advocacy Advisory Board, a member of the Education and Research Foundation for Nuclear Medicine and Molecular Imaging Board, the treasurer and a board member of the Neuroendocrine Tumor Research Foundation, and the president of the NorCal CarciNET Community. In addition, he is a U.S. Food and Drug Administration (FDA) patient representative, a member of the National Cancer Institute's Gastrointestinal Steering Committee, a member of the American Society of Clinical Oncology Scientific Committee, and the sole patient representative on the Nuclear Regulatory Commission (NRC) Advisory Committee on the Medical Uses of Isotopes (ACMUI). Mr. Mailman has an MBA from the UCLA Anderson School of Management and has been a technology entrepreneur for more than 20 years.

**Dr. Hope:** *Could you start by talking for a couple of minutes about your diagnosis, what you remember about that time, and what nuclear medicine meant to you then?*

**Mr. Mailman:** What is nuclear medicine? As a newly diagnosed patient you have no idea. I think one of the more amazing aspects of my journey is that last year I became the patient's right advocate on the NRC ACMUI. Fifteen years ago, when I was diagnosed, I knew neither that the NRC had anything to do with nuclear medicine nor that there was an advisory committee I might be on.

As to my diagnosis: this was an incidental pick-up during an annual exam. I recommend that everyone continue annual checkups for this very reason. I'm the son of a doctor so am pretty religious about following up. At my annual exam in 2007, my checkup went well, my blood work was fine, but my general practitioner felt something a little weird under my rib cage and told me to get an ultrasound when I had some time. Two months later, I had a chest cold that brought me to urgent care, where the staff said, "It says here you need an ultrasound, so why don't you go while these other tests are being run?" I went for the ultrasound, and as I was coming back no one on the urgent care team would look me in the eye—my first indication that something was wrong. There was a finding on ultrasound, and I was scheduled for a CT, which showed a very large pancreatic mass. The biopsy showed a neuroendocrine tumor (NET). This led to my first nuclear medicine study, an OctreoScan (Mallinckrodt), which led to appointments with an oncologist

and surgeon. Not many treatment options were available in 2007/2008 for a non-functioning pancreatic NET without a surgical possibility.

About 4 mo into my journey, I joined a support group for patients with NETs. The group was big on education and advised me to go to patient conferences and learn about this disease. The first patient conference that I attended was a two-day meeting in Toronto. The first day focused on surgery, somatostatin analogs, and more somatostatin analogs, and none of it applied to me. At the end of the day, I was pretty depressed, because I hadn't seen any possibilities of learning anything new.

On the morning of the next day, presenters from Europe discussed <sup>68</sup>Ga imaging and radioisotope therapy. All of a sudden, I was where I was supposed to be. I'm a tech guy. I cocreated eFax.com; I like more data and innovation. The first lecture I saw was from Richard P. Baum, from Germany, who presented data about how we can see more disease and see it more clearly and with greater accuracy than was standard at that time. I walked up to Dr. Baum after his presentation and said, "Where can I get one of these?" And he said, "In Germany in three weeks." And so, my journey in nuclear medicine began.

**Dr. Hope:** *Can you talk about the role of patient advocacy groups and how they benefit the community? Looking forward, how do you see their role changing or expanding to help improve patient care?*

**Mr. Mailman:** Patient advocacy groups are really important. First, I'll talk about patient support groups. As patients we all come to clinics, sit in the lobby, and none of us talk to each other about our disease. I went months without meeting anyone who looked like me or had anything that we could relate to, even though I was probably in waiting rooms with them all the time. No one goes around and says, "Hi, I have a neuroendocrine tumor; what's your name?"

A support group is a safe place to discuss your journey. I could meet people like me, hear about what other people were doing, and learn from that shared experience. I was fortunate to find a group that valued education and that reached out to our medical community to work with them. This relationship has been a major driver in northern California, making sure patients are comfortable with their treatment decisions/plans. As patients, we may get at most 30 min with our physicians, at a time when we're very stressed. The support group is a safe place to have a conversation about care, what you're doing, and what is new that's coming up.



Josh Mailman, MBA

The interesting part about these independent support communities is they can provide support in a way that doesn't feel rushed. One of the hardest things to convey when I talk to institutions that are interested in starting support groups is that, as a patient, I don't want to spend more time in your 4 walls. We feel different emotions when we walk through the doors at a hospital, and I'm going to spend as little time there as possible. Independent support communities don't have that weird feeling of "this is where I get treated."

**Dr. Hope:** *I would just add one thing, which is the importance that your group in particular and other support groups and patients in general have for people's careers, including my own. Travel grants provide opportunities to give lectures, participate in activities that help develop the community, and bring new investigators into the field.*

**Mr. Mailman:** That was one of the reasons we decided to become a nonprofit more than 10 years ago. We wanted to be able to give back to our community, to support not only patients but those who support us in our community. Our educational and travel grant program helps us support those interested in NETs, which, in turn, will help us as well. It's a symbiotic relationship. This is really about our community serving our community.

**Dr. Hope:** *You, like many people with serious disease, but particularly NETs, have gone to Europe to receive peptide-receptor radionuclide therapy through compassionate use and have benefited greatly. Can you talk about your thoughts on compassionate-use laws, their impact, and how you think about this as a patient?*

**Mr. Mailman:** This is a challenging topic. You and I work in the clinical trial environment of the National Cancer Institute, where we're trying to bring forward practice-changing clinical trials. I've

**Dr. Hope:** *You've had several roles over the years. Which one do you think has had the greatest impact on patients?*

**Mr. Mailman:** That's an interesting question. I think the most impactful was my work with the <sup>68</sup>Ga Working Group. In 2011, I had a chance meeting with Henry VanBrocklin, from the University of California, San Francisco, while at dinner attending the first Theranostics World Congress in Germany. He was, at that time, the head of the SNMMI Patient Outreach Committee and invited me to join the Patient Advocacy Advisory Board and the <sup>68</sup>Ga Working Group. This was long before we had trials going on with <sup>68</sup>Ga, and, through the working group, we wrote the imaging manual for <sup>68</sup>Ga PET, which turned out to be the imaging manual that everyone in North America used. It was really important to bring the patient voice and urgency to our monthly meetings and to writing that imaging manual.

Through that committee, we persuaded the FDA to come to the Third Theranostics World Congress in Baltimore, MD, in 2015. We had 70 patients there on a Saturday listening to the FDA say that plenty of trials were going on. The patients responded that there were few and that new ones were needed now. The FDA basically said then and there that they would approve or expand Investigational New Drug approvals and encourage the filing of a New Drug Application for <sup>68</sup>Ga.

I have also worked to raise in excess of \$20 million for NET research, and this has helped move progress forward. It has encouraged or kept researchers interested in the field. Those researchers will make significant discoveries and increase the number of people who provide patient care, ultimately impacting the patient experience.

So having dinner with Henry VanBrocklin in Germany, which led to my participation in the SNMMI <sup>68</sup>Ga Working Group,

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benefited from what really are not clinical trials but compassionate use, the early use of therapies in patients. It allows therapies to get into patients earlier and may give us some signaling about benefits and results. That's great, but it's challenging when it becomes the only avenue by which a therapy can go forward.

It's a dichotomy I've benefited from, but it's useless unless it goes toward informing a registration trial. We're not benefiting the majority of patients—and that is what we need to be doing, going toward registered products. If we're going to use this avenue, it's really important that we push toward trials that produce data that can be used to inform registration. I'm encouraged by what's happened in the prostate-specific membrane antigen field. Yes, there was early compassionate use, but this moved to clinical trials (such as VISION or TheraP) much more quickly than we did with NETs.

**Dr. Hope:** *Can you comment on the United States, where access to compassionate use is much more limited? Is there anything you think about the way we approach the regulatory status here that might help move things forward?*

**Mr. Mailman:** This can be done individually. <sup>90</sup>Y-DOTATOC was used in Iowa for a while, but it's tough. It's a different environment, and the question is: How do we get movement toward phase I trials earlier? In the NET space, we didn't have an investor who was interested in taking trials further in the early years. The environment has changed; people are seeing market opportunities more quickly. I'm not even certain that, if we changed the regulations, our institutions would do this kind of work without some type of pharma backing, which would defeat the purpose of trying to do it.

which moved us toward approval on a landmark imaging agent, has likely had the most impact on patient care.

**Dr. Hope:** *On the other side of that story, you've been involved with the FDA in different ways. Can you comment on the leadership of Lou Marzella, as the director of the Division of Imaging and Radiation Medicine in the Center for Drug Evaluation and Research at the FDA, and how he's adapted over time?*

**Mr. Mailman:** I first met Dr. Marzella in Baltimore. I think he was pleasantly surprised at the patient involvement—it was eye opening to hear patients come forward in that number and speak so eloquently. Over time we became friends in advancing patient care. We started emailing each other when issues came up or for clarification about the regulatory framework, for example in the early days of <sup>68</sup>Ga. We held <sup>68</sup>Ga sessions at all the annual meetings at which he spoke. The friendship became such that he started inviting me to give talks to the imaging directors' lunch at the FDA. It was a little intimidating to be a patient speaking to 10 imaging directors, giving my perspective on the challenges of getting these drugs to patients. Every interaction I have had with Lou and the imaging group at the FDA has been positive.

One of the last times I had lunch with them, I discussed the challenges associated with <sup>68</sup>Ga generators and how few generators were available. The FDA gets outage reports for every drug that is prescribed, but they don't have insight into radiopharmaceutical supplies. It was again patients who brought insight to the FDA about this access issue, and I think they've appreciated that.

Lou has been a champion of the patient, moving things forward and making sure that there's transparency in the process.

**Dr. Hope:** *How did your life before your diagnosis help you deal with cancer and be more effective in the role you have now?*

**Mr. Mailman:** My background is in business. I have a master's in finance and marketing from UCLA and worked in technology for more than 20 years. Developing new products in technology, you learn a great deal about patents and proprietary rights. The first set of meetings of the <sup>68</sup>Ga Working Group was all about patents and rights. We didn't really talk about drugs; we talked about patent expirations and marketing exclusivity to better understand how this imaging agent could come to market. That was right up my alley, because that's what we did in tech all the time.

My business background has helped the ways in which I run our support community. One of the things that I learned in graduate school and marketing is that there needs to be a drumbeat—something constant that people can count on. Consistency matters. We meet on specific days—the first Saturday of every other month for us in Walnut Creek.

**Dr. Hope:** *Switching topics here: What do you think is the next exciting thing for NET patients? What are you most excited about?*

**Mr. Mailman:** I'm going to answer a different question: What is the most exciting NET project I am working on? As you know, since you have been running with us at our annual charity run, we have shirts that remind us of the people we've lost over the last year. It is a constant reminder that we don't live forever. We don't do much for those who are facing end-of-life decisions. A NET patient may have spent years trying to find a NET specialist, but once beginning hospice care, he or she will see a generalist, who may not understand NETs at all. I have personally worked with several patients who have struggled with this transition. I am currently working to change this with guidance to help providers with patients as they enter hospice. It will cover the unique aspects of NETs that differ from other end-of-life scenarios. My hope is that it will be easier for those who are nearing death, because their care team will be able to better understand and comfort patients at the end of the journey. Over the years that part of this journey has been the most challenging, and we have to do better.

**Dr. Hope:** *That's a great point, particularly for nuclear medicine, where we usually come in for a portion of time and then go away. We do peptide-receptor radionuclide therapy, for example, and then we're out.*

**Mr. Mailman:** Several times a year I work with hospice patients' families. One example is when patients have hormone-producing symptoms but are taken off long-acting somatostatin analogs and can no longer get access to long- or short-acting somatostatin analogs. 2021 was a tipping point, with a patient who called me and asked if I could help him because he'd been in hospice for a month and his symptoms were getting worse. His hospice basically denied access to long- or short-acting octreotide. This went all the way up to the board of the hospice. The patient called me to say that he was about to exit hospice for 72 h, so that he could get a long-acting administration. In that 72 h, all the durable equipment that he'd come to use (beds, etc.) would have to be removed from his house. The whole process just got me angry. This was the impetus to ask the North American Neuroendocrine Tumor Society Guidelines Committee to write an end-of-life white paper. We have about 7 of us on the project at the moment

I'm also working with pharmaceutical companies in the background. Hospice gets \$270 a day for nursing care, all meds, and all visits, so even if it's prescribed, most of them will not want to use it because it is too expensive, and I'm trying to solve that. This is the most important thing that I'm working on currently. It has nothing to do with what I normally do, but it's just so important that we work with patients all the way through their journeys.

**Dr. Hope:** *That is a perfect way to end. In this series we always talk about the next peptide, the next drug. What you bring to these discussions is patient centricity. You really highlighted why we do this, which is the patient. Sometimes we get lost in the science, the drugs, and the research. You did a perfect job of bringing us back to what matters: the patient.*

**Mr. Mailman:** It's the journey. We all talk about how we're going to make people live longer, but we're not going to make them live forever.