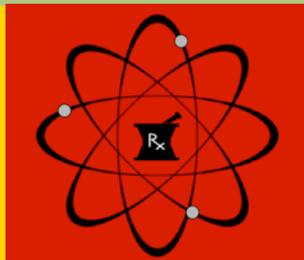


# The Nuclear Monthly Missive

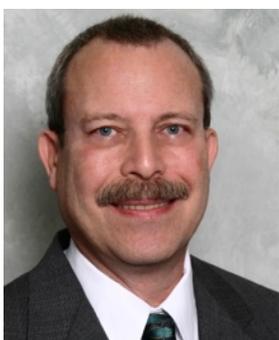


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## Unstoppable

The year is 1970, and Kenneth Breslow has just finished pharmacy school at the Brooklyn College of



Pharmacy in New York. His dad owned a small retail pharmacy in Queens, NY, but Ken always knew that retail pharmacy was not for him. He is hired as a pharmacist for the Veterans Affairs (VA) hospital in Manhattan, where he spends most of his day preparing vials

of total parenteral nutrition (TPN) in the hospital's newly-acquired laminar flow hood. Tired of The Big Apple, he desired to reside in California, so he transferred to the VA in Long Beach. Shortly before his move, a friend told him about this little niche within pharmacy called nuclear pharmacy. "Sounds intriguing," he thought. He also learned that the VA sponsored two pharmacists each year to complete a Masters of Science in Radiopharmacy at the University of Southern California, followed by a residency under Walter Wolf. "The VA paid for everything; my move, tuition, and even living costs." Jackpot! It was during this program that his passion for nuclear started, and even today, it is unstoppable.

After finishing his residency, Ken continued to work for a short time as a staff pharmacist at the VA hospital, but in 1974, he was offered the position of Chief Radiopharmacist for Imaj International, a new division within Allergan Pharmaceuticals in Irvine, California. In this role, he participated in bringing

### Did you know...

Did you know that the first formal gathering of nuclear pharmacists was held by APhA at the 1974 annual meeting?

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new and innovative nuclear pharmacy products to market, such as the automated Tc-99m generator based on methyl ethyl ketone (MEK) extraction. Because the company was also developing cold kits, Ken was responsible for performing bio-distribution studies. And this is where the stories of industry shenanigans begin. "Have you ever tried scraping muscle off of bone?" he asks as he chuckles. "Um, excuse me?" At this point, I wasn't sure if we had somehow switched from discussing bio-distribution studies in animals to discussing alternative dining techniques. He repeated the question, specifying that he was referring to a rodent, but I responded with a simple, "Negative." Apparently said process can be quite difficult, so to make it a bit easier, Breslow determined that if you flash-cooked the carcass in the company's autoclave, the meat "just falls right off the bone... but it stank up the entire building". Good to know.

"The best part? I was helping people every day, directly and indirectly."

Despite his clever conquests, the company did not last, and in September of 1974, Ken was laid off. Between jobs, Ken converted a thirty-foot bus to a camper and toured the western states. His bus stopped next in Iowa at the University of Iowa, where he took a joint appointment as a clinical assistant



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Suggestions for next month's newsletter? Contact Ashley Mishoe at [AshleyMishoe@me.com](mailto:AshleyMishoe@me.com).

professor with the College of Pharmacy and as the Nuclear Pharmacy Director for the hospital. In addition to setting up a nuclear pharmacy lab and initiating the nuclear program within the Colleges of Medicine and Pharmacy, he was in charge of designing clinical trials for the hospital. Downside to



this position? Winter in Iowa. And he lasted for exactly 3 of them before insisting on a

warmer climate. “Upside,” he says, “I discovered that I really enjoyed teaching, and some of my first (and favorite) students were Jim and Laurie Ponto”.

From there, Ken moved to Albuquerque and served as both a Clinical Assistant Professor and the Assistant Director of Preclinical Research at the University of New Mexico under Dr. Buck Rhodes. During this time, he was involved in early research with iodinated and technetium-radiolabeled antibodies. He explains that they “were one of the early teams to produce clinical images in human cancer patients with labeled antibodies,” adding “I still remember the thrill that I experienced”. One company that was funding this research at UNM, Summa Medical, decided to pursue their own research rather than continue to contract through the University. The company hired Mr. Breslow as the Director of Manufacturing, and he was responsible for further development and clinical trial design of radiolabeled antibodies, as well as designing and equipping their research lab and GMP pilot antibody production facility. Unfortunately, the company did not succeed in their efforts. Again, Ken fell victim to industry lay-offs. But again, he did not stop.

Ken was drawn back to California (which he dearly missed) with a position as the Director of the Pharmaceutical Technology Laboratories at the UCLA Medical Center. Although this role contained

zero nuclear involvement, he tells me that “everything learned in previous jobs helped in this one”. This center supplied TPNs for both inpatients and outpatients, and it was the largest of its kind in the country. And by “largest of its kind” I mean 80,000 liters compounded from scratch each year, as well as 100 injectable products and the compounding of any other dosage form imaginable. Yeah, that big. Ken was deeply involved in clinical research at UCLA and even helped develop some of the innovative therapies used today. He describes the processes there as “large-scale compounding/small-scale manufacturing”. Sounds like a place the FDA would love to visit! By the time Mr. Breslow decided to change focus again, he had turned the pharmacy’s basement-like facilities into a 7000 square-foot GMP-compliant establishment, complete with 3 sterile suites. Although Ken was burned out at UCLA and was in need of a break, he kept going.

In 1993, he was contacted by Centralized Admixture Pharmacy Services (CAPS) to develop and manage this new company’s pharmacy services. CAPS was one of the first large-scale, commercial compounding pharmacies, and Ken was hired not only to develop manufacturing processes of their sterile products, but also to implement quality control procedures and train new staff on the procedures. When the company’s lofty goals of exceeding 20 new sites in a year fell flat, a few of the “expendable jobs” were cut. “Uh oh,” I sputtered; I knew what he was going to say next. Ken laughed and admitted that yes, of course, his job was one of them. Luckily, his sense of humor and positive outlook helped him stay enthusiastic about the loss of yet another job. So did he stop? Of course not. He pushed forward. He decided to get back to his original plans. . . back into nuclear pharmacy, but something different this time.

“FDG is amazing!”

Enter Syncor (which joined forces with CTI to form PETNET Solutions), and enter the start of his PET career. This segment commenced in late 2002 and it lasted for 19 years. Ken began his fresh start with the company in LA as a “radiopharmacist intent on transitioning into PET,” but it wasn’t long before the

company recognized his expertise in quality assurance and regulations. He moved from LA to the company headquarters in Knoxville, Tennessee, where he spent the past 11 years providing GMP training to employees and submitting INDs, ANDAs, and other regulatory reports. Also during this time, he actively participated with regulatory authorities in the development of regulatory standards for PET. With the ever-changing governmental regulations on the profession, Ken was forced to keep abreast of the latest guidelines to ensure that the company's procedures followed along.

Ultimately, as the Senior Regulatory Affairs Specialist, he was a vital component in the company's transition from compounding to manufacturing. And for that, they are thankful to be his last corporate stop before (semi)retirement.

Mr. Breslow's drive wasn't only at the career level, either. He became an active member of APhA as a student in 1966. During his course, he has served on numerous committees, served as the Section Chair in 1980, and is now an APhA Fellow. Oh, and did I mention he was recognized by APhA as one of the Top 40 Pioneers in nuclear pharmacy? Fact: This year's annual APhA meeting is the first one he has missed in over 20 years. (We missed you too, Ken!) He has also held leadership roles with SNMMI, sat on the Board of Directors of CORAR, and was active in the Parenteral Drug Association (PDA). In SNMMI, Ken is a member of the Radiopharmaceutical Sciences Council, the Government Relations Committee, as well as a key leader on the Coalition for PET Drug Approval. Through all of these appointments, he was able to apply his expertise in the field and his prior experiences to much larger goals. Publications, you ask? Yeah, he's Pubmedable. From his first article on tumor uptake of a technetium-tetracycline complex in the *Journal of Nuclear Medicine* in 1974, to his latest manuscript in the *PDA Journal of Pharmaceutical Science and Technology* regarding FDG purification processes (found [here](#)), he has spread his knowledge in a myriad of outlets, including scholarly journals, book chapters, educational programs, and professional presentations. He even holds a patent on the use of choline salt in TPNs. Quite impressive!

At the end of the day, the best part of his (many) jobs was knowing that "I was helping people every day, directly and indirectly". For him, the thrill wasn't found in the monotony of drawing doses or being sentenced to shift work, but doing different jobs and never doing the same work twice. He tells me that "FDG is amazing! And helping a product like that succeed, and knowing you helped get that product to the larger market, well *that* is amazing." And helping people drove his passion in his profession every day.

His plans for retirement? Perhaps he will return to the classic car hobbyist he has been since 1986. (His favorite was



his '52 Hudson Hornet.) Maybe someday, but not yet. He can't stop just yet. For now, he continues to provide knowledge and guidance to others in the field of PET via his consulting firm. He foresees nuclear pharmacy only getting more sophisticated and more challenging to use, and he adds that the challenges and advances with PET are only beginning. Ken suspects that although more challenges are in our future, the profession will also see new paradigms coming together with PET being a critical new tool in therapeutics development. Back to the basics of molecular science? Perhaps. As for students and new practitioners, his advice is to "follow your passion. Engage yourself in something that inspires you and encourages use of your imagination. The profession of pharmacy has so many avenues open to you". Become a BCNP, as it forces you to learn more and to become a better professional. (He was with the first batch of pharmacists to pass in 1980.) Be passionate. Be persistent. Be like him; be unstoppable.

Until next time,

Ashley Mishoe