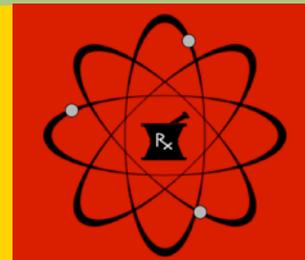


The Nuclear Monthly Missive



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Designer by Trade



She started sewing at the age of four. “Colors. . . textures. . . patterns. . . the art of dressing, the art of *design*.” I can still hear the passion in her voice as she assures me that “fashion design is my true love.” Her name is Sally Schwarz, and she is a fashion designer. Oh,

and she’s also a nuclear pharmacist!

“I always wanted to be a fashion designer, but my mom said, ‘No’ -- but only because she wanted me to be able to support myself.” Sally’s father was a pharmacist and was the owner of two specialty pharmacies in Clinton, Iowa. She started working for her father at Wagner Pharmacy when she was 14, and she loved learning about the chemistry behind the drugs that were dispensed and the way the drugs were formulated to work. Pharmacy was an easy option; it made sense.

Ms. Schwarz completed her Bachelors of Science in Pharmacy at the University of Iowa in 1971 and stayed in Iowa City to begin her career with the Veterans Affairs Hospital. During her two years there, she saw an advertisement supporting traineeships in nuclear pharmacy in an effort to provide nuclear pharmacists for the VA Hospital system. She tells me that her pharmacy program in

Iowa had touched on nuclear pharmacy, but that it wasn’t exactly a field. . . yet. Sally felt that nuclear pharmacy was a developing field, and in 1975, she began the Masters of Science in Radiopharmacy program at the University of Southern California. “The program was very intense,” she tells me. Her coursework included radiochemistry, nuclear physics, dosimetry, radiation biology, and regulatory affairs, and Sally admits that the curriculum is all still relevant today. While in the program, she also completed laboratory exercises that included production of kit formulations for preparation of Tc-99m radiopharmaceuticals (RaPh), analytic techniques such as column chromatography, and animal

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biodistribution studies using rectilinear scanners. “Dot-dot-dot, dot-dot-dot-dot,” she describes the output of the scanner, equating its sound to that of a dot matrix printer. After completion of the one-year program, Ms. Schwarz was recruited by Michael Welch, PhD, to Washington University in St. Louis for a joint appointment in the Clinical Nuclear Medicine and Radiological Chemistry Divisions. WU Nuclear Medicine was just replacing their last rectilinear scanner with a state-of-the-art gamma camera. “I began at a time when a lot of change was occurring” in the field of nuclear pharmacy. CT imaging had just been



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introduced and was replacing nuclear medicine brain imaging because of its ability to better define brain anatomy. But as this procedure dissipated, other areas of imaging, such as cardiac imaging, were beginning to expand.

At the same time, research at WU involved use of a PET scanner developed by Michel Ter Pogossian. PET brain imaging was being performed focusing on activation studies (i.e. stimulating various regions of the brain through tactile, visual, and audible methods), using injection of O-15 water, which allowed for observation of increased uptake in certain regions of the brain. One of Sally's first PET research projects was radiolabeling microspheres with Ga-68 that was produced at WU, using a solvent extraction generator! She collaborated with a chemist from 3M for this project and submitted an abstract on their work. Sally laughs and says, "I was in a world of chemists," as she recalls how difficult it was not having an in-house nuclear pharmacy colleague to brainstorm with.

In 1978, Sally was in need of a change, so she decided to pursue her true love, fashion. Fashion design, radiopharmaceutical design -- they're essentially the same, right? Her friend, Margi, was well-connected with the fashion industry in New

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York City and taught Sally the essentials of pattern-making and clothing design. And it wasn't long before her childhood hobby

became her 5-year sabbatical from nuclear pharmacy. She started in the back of then-friend-now-husband's plant shop in St. Louis, where she and Margi partnered in creation of a clothing boutique named Mariposa, meaning butterfly in Spanish. Specializing in unique fashion trends for women, (including hand-painted tuxedo shirts sold on Rodeo Drive), the boutique offered vintage finds, as well as pieces designed and produced by Sally and her partner. They travelled often to NYC and California selling their pieces and searching for new ideas, and Sally was happy to have this adventure.



But after a few years of feeding this passion, she was ready to return to life as a pharmacist. "I had gotten married, had a little girl, Amy, and now it was time to return."

Mariposas in her stomach, in 1984, she reached out to her former boss in hopes of securing a position back at Washington University Hospital in St. Louis. His thoughts on her return were made obvious when he asked, "Can you start tomorrow?" She returned to a position that was half clinical and half research. Her research primarily focused on radiolabeling antibodies with In-11 and Cu-64, and because of her chemistry background, she authored the chemistry sections of the three INDs for these research agents.

In the clinical realm of her position, Ms. Schwarz managed the hospital's nuclear pharmacy, created kits, and performed in-house endotoxin testing using rabbits. (Thank goodness we have advanced to the PTS endotoxin test!) She also was responsible for implementing the radiopharmacy/radiochemistry training program for both nuclear technologist students and nuclear medicine residents. She enjoyed giving lectures and training students on antibody labeling, adding to the courses as her research progressed in this area.

Formerly under the Department of Radiology, the nuclear pharmacy underwent an organizational realignment in 1995, and fell under the leadership of Barnes-Jewish Hospital's Department of Pharmacy. With the new shift, Sally decided to stay with the Department of Radiology and began managing the production of F-18 FDG. Although the change was gradual, she essentially started from the ground,

creating Standard Operating Procedures (SOPs) for an older cyclotron facility that was used for production of clinical research PET RaPh for human use. She describes the beginnings of the facility as a “chemistry-run operation,” stressing the challenges of combining aseptic techniques required in pharmacy to the bench-top habits of chemists. She admits that this was an arduous journey as she was initially targeted as an intrusion into their area, but they quickly learned how valuable she was to the success of the clinical research. She explains that she was on “the island and had to build bridges to make it work,” but that ultimately she was able to join the two and “it worked very well.”



Sally is currently the Co-Director of Washington University in St. Louis’s cyclotron facility, which has three cyclotrons and a fourth on the way. (Fun fact: the first medically-used cyclotron was housed at WU. It’s true; Google it.) In this position, she still works closely with chemists in the development of new radiopharmaceuticals and oversees the quality assurance of over twenty research drugs, including C-11 Pittsburgh compound B (PIB) for Alzheimer’s imaging, F-18 FDOPA for movement disorders, and a Zr-89 labeled Herceptin MAb for detection of HER2 receptors. Sally led the facility’s efforts in submitting two Abbreviated New Drug Applications (ANDAs) for F-18 FDG and N-13 ammonia, and she writes Chemistry, Manufacturing, and Controls (CMCs) for the hospital’s Radioactive Drug Research Committee. Additionally, she is involved with the University’s multi-site clinical trial involving C-11 PIB as a biomarker for several therapeutic agents. She will quickly tell you that she is not the *designer* of new agents, but ensures that they are safely implemented into patients.

As the wearer of many hats, Sally’s day-to-day activities range from regulatory affairs,

radiopharmaceutical production, and staff management, to quality assurance and maintenance. When asked what she enjoys most about her job, she proudly states, “the delivery of a quality product for human use, all the time.” She continues describing the process of a cyclotron facility becoming cGMP-compliant, and stresses the high standards that must be achieved -- standards that Sally implemented from day one. “I have always encouraged education,” she tells me, and because of her persistence in assuring compliance, she also ensures that she is available to help her colleagues accomplish these feats.

Sally has been involved in the advancement of the profession of nuclear pharmacy from quite a few angles. She is the Co-Director for the Coalition for PET Drug Approval, an organization that seeks to help the PET community fully understand FDA regulations surrounding NDA and ANDA submission. She is on the USP Physical Analysis Committee, previously served on the Advisory Committee on Medical Uses of Isotopes (ACMUI) with the NRC, and was President of the

“I began at a time when a lot of change was occurring.”

Radiopharmaceutical Sciences Council for SNMMI. Sally has always been fascinated by regulatory requirements and started attending FDA workshops in 1995 (prior to FDAMA) to ensure her knowledge base kept up with the changes. In response to her roles with these groups, she says, “Regulations are important and are always going to be part of our lives, so I continuously look for something more I can learn and can teach to someone else.” Because her first mentor was a chemist, her focus was

directed toward the chemistry aspect. She became very involved with the International Society of Radiopharmaceutical Sciences, an organization that focuses on the design and synthesis of radiopharmaceuticals, and since her start with the organization, Sally has been instrumental in getting other pharmacists more involved. Sally now serves as this Society's treasurer, and stresses to members the importance of pharmacy involvement in new drug development. Although she was involved with APhA more distantly, the Association recognized her achievements in pharmacy and honored her as an APhA Fellow.

Because of her ongoing research, I was anxious to learn what Ms. Schwarz sees for the future of our profession. She tells me that she hopes that "it continues to grow because of the ability of PET." Sally stresses the importance of the newer PET agents not only in diagnosis, but also in monitoring the progress of other therapeutic drugs, and she is confident in what lies ahead in this science. She adds that "the beauty of radiopharmaceuticals is the tracer-level of definition" that is available, and she is confident that this science will continue to grow and develop in the years to come, just as it has during her career.



Did I mention she loves design? No, seriously; she does. And not just clothing design (and drug design and cyclotron facility design), but also interior decorating and gardening. Sally finds happiness tending to her bulbs and creating her new backyard water feature. She loves the colors the flowers bring and says that the continuous blooms are a source of inspiration.

"Be open to change," Ms. Schwarz eagerly advises to those considering a career in nuclear pharmacy. She tells me that although she left nuclear pharmacy practice for a several years, she came back because she liked it -- and she stayed because she likes it. And she encourages you to do the same. "If you are motivated," Sally hints, "there are always more opportunities." First job not as dreamy as you thought it would be? Pick what you like most about

it, examine other paths, and move forward. For her, "nuclear medicine has been an exciting career, a challenge." Find the beauty in designing your own way, foraging your own course of direction, never stopping until you have found your passion.

Until next time,

Ashley Mishoe



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