Telecommunications, Environment/Energy and Health

Carole C. Carey

Being an enthusiastic martial arts student and fascinated by the teachings of the Japanese traditional martial arts, *taijutsu*, I became more involved in training in the *Bujinkan Budo Taijutsu* system. Whenever there was a chance, I would go to Japan and train directly from the *sōke* (grandmaster) in Noda, a small city located in the far northwestern corner of Chiba Prefecture. As I progressed in my training and became more familiar with the surroundings in Japan, it fueled my desire to know Japan profoundly—its history, its culture and its people.

So, when I heard about the Mike Mansfield Fellowship Program from a friend who talked passionately about his wonderful experiences and the positive effect on his career post-Fellowship, I was very excited about the opportunity. I would be living in the country that mesmerized me and be totally immersed in a culture where I could really get to know the people of Japan. Professionally, I have skills and knowledge to offer Japan. I want to be part of the core group of U.S. government officials who serve as a resource to my agency, the Food and Drug Administration (FDA) Center for Devices and Radiological Health. Awesome!

However, with excitement there was also great fear. Could I really learn a new language that is so different from any of the other languages I know? Is the ten months of language and area studies training in the Washington, D.C. area enough to prepare me before departing for Japan and to work effectively in Japan's Ministry of Health, Labour and Welfare (MHLW)? As one of seven federal government employees in my group chosen for the Fellowship Program with the least language experience, will I be successful in improving Japanese-American relations?

Little did I know just how much I would learn from the year-long experience that followed the language and area studies preparation. Tokyo and the other cities held sights and sounds that were different from living in the United States. Precise on-time overcrowded trains, street addressing systems that made finding the meeting venue challenging, spa-like relaxing public baths (*onsens*), street festivals, shrines, temples, sumo and so forth just made it much more interesting and memorable.

Yet, the most important single element of success that the Mansfield Fellowship Program provided me is the opportunity of working closely side-by-side with my government regulatory counterparts. In an environment that was unfamiliar, I learned empathy and soon overcame my uneasiness. I remember vividly great advice from an experienced State Department official. I asked the well-traveled official, "Do you think the Japanese will accept me as a peer?" He said, "Be yourself, do not act like you are Japanese and you will be fine." He was right! That was all I needed to know. How I knew when the cultural barrier was broken and the bonds of trust were established is just something you feel.

Japan MHLW and the United States FDA have long-standing bilateral relationships—sharing information on device safety, effectiveness, and adverse events, addressing medical devices issues and working cooperatively to find common solutions. We both have well-established regulatory frameworks, with the U.S. having more experience (being around much longer) and having learned from our mistakes. Approval of devices in Japan typically lags two to three years behind the U.S, so there is strong desire to collaborate and promote harmonization in order to shorten the time lag and make innovative devices available globally at about the same time and accessible to patients who would benefit from them.

In 2002, Japan had just passed and enacted the revised Pharmaceutical Affairs Law. Feeling very fortunate to be working with them in the midst of the implementation, I tried to learn about their system. At the end of the Fellowship, I was confident that I gained a deeper understanding of the regulatory policies and practices concerning both the premarket and postmarket life cycle of the device. The Japanese also had a thirst for knowledge and are very smart. Their English was much better than my '*Nihongo* basics,' so we carried out our conversation mostly in English. Happily, I shared my knowledge and experience. As an expert regulatory review scientist (electrical engineer), they also used me as a resource in their review of applications that contained clinical data in English.

At least once a month or so, I was asked to give a seminar on topics they selected that would be of most interest to them and relevant to their review work assignments. The interaction was informal, engaging and they asked questions freely. Sometimes, their perceived interpretation of our regulations may be different than the intent of our regulation and need to be clarified.

Another exciting occurrence during my Fellowship was the issue of availability of automated external defibrillator (AED) as public access defibrillator in Japan. The Japanese Medical Practitioner Law stipulated that only qualified doctors are permitted

to use AEDs. Many physicians and the public supported the use of AEDs among non-medical rescuers. Since July 2004, any citizen in Japan can use an AED legally.

In Tokyo, I visited the Tokyo Metropolitan Government Fire Department Emergency Medical Division, the Fire Disaster and Management Agency (FDMA) and the National Safety Council Japan to discuss AEDs and public access programs already existing in the U.S. As a scientific reviewer of highly complex cardiovascular devices, I also worked significantly on safety and effectiveness review evaluations of AEDs for lay use, and promoted the American Heart Association's chain of survival as well as supported the expansion of widespread installation of AEDs in airplanes, public places and home use. Defibrillators are near and dear to my heart as my father died of cardiac arrest and no defibrillator was available.

I forgot to mention, my Japanese friend Susan came with me when I visited FDMA. Susan's family and our family continue to exchange e-mails. When I read her March 12, 2012, message, something made me feel good and humanitarian and that perhaps I made a contribution to society in a small way, not just in the U.S. but in Japan as well. Susan said, "Carole will be pleased to know that there are AEDs everywhere now in Japan. She had a lot to do with its implementation."

Post-Fellowship, there has been no break in our continuing cooperation and bilateral programs with Japan. Our two major programs are the Harmonization By Doing and Collaborative Consultation and Review of Premarketing Applications, which I manage as part of my responsibility in my current position as Director of International Staff in the Division of Small Manufacturers, International and Consumer Assistance.

We are leveraging each other's resources to be efficient and avoid duplication. Our goal is to continue the pace working towards accelerating regulatory convergence and communicate through think tank meetings, regularly held monthly telephone conferences, e-mail correspondence and, when possible, face-to-face meetings. Our FDA Center for Devices and Radiological Health also hosted MHLW officials under the Mansfield U.S.-Japan Healthcare and Medical Devices Exchange Program.

The Mansfield Fellowship Program is effective. It has indeed contributed greatly in advancing the understanding and cooperation of U.S.-Japan relations. To participate in such a unique program where I can exchange ideas with colleagues in my counterpart agency in Japan is a rare opportunity. The pathway to global product safety and quality is engagement. I feel the Fellowship helped build solid professional relationships to improve the communication between the Japanese and U.S. governments.

Carole C. Carey participated in the Mike Mansfield Fellowship Program as an expert regulatory review scientist and representative of the U.S. Food and Drug Administration from 2003–2005. During her Fellowship year in Japan, she served a full-time placement in Japan's Ministry of Health, Labour and Welfare (MHLW) and its review arm, Japan's Pharmaceutical and Medical Devices Agency (PMDA). She currently serves as an advisor on international relations and external affairs at the U.S. FDA, Department of Health and Human Services.