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A past president of the SIR discusses her views on the importance of clinical practice and her experiences at the FDA.

How has interventional radiology and the SIR changed since you were president in 1996-1997? There has been a significant amount of change, although I think it was already occurring when I was president—it has been an evolutionary thing. I think the most significant aspect is the change is from a practice where we were simply asked to perform procedures on patients to a practice in which there is much more of a clinical focus, with procedures only being part of what we do. This change had already started and was talked about a lot when I was president, but I think in the last 7 years or so, interventional radiology has really become much more clinically focused than it ever was before.

Accentuating the trend, the recent SIR meeting focused heavily on clinical application and patient interaction. It did, due the recognition that we are not technologists, that we need to see patients before we perform their procedures, talk to them, make a plan with them, perform the procedure, and then conduct their follow-up. There has been a real push for centers having clinical time, and this has been something that interventional radiology has been striving toward for a number of years. We now have more buy-in from radiology groups for interventional radiologists to do this, and, 2 years ago, the American College of Radiology passed a resolution indicating that interventional radiologists needed to have a clinical practice.

Following the resolution, a group headed by Jim Swischuk, MD, and David Sacks, MD, developed guidelines for interventional clinical practice. These guidelines indicate that interventional radiologists should accept referrals for therapeutic interventions, perform consultations prior to and after interventions, establish treatment plans, admit patients, and provide longitudinal patient care. Of course, in order to practice this way, the interventionalist requires support, which may be different than what is found in a traditional radiology practice. Such support includes personnel, such as nurse practitioners and physician assistants.

A clinic space that is appropriately equipped is required, as are administrative resources (such as schedulers, coding and billing, and insurance precertification), a database for tracking procedures, outcomes and follow-up, and most importantly, time to see patients. These guidelines, which are on the ACR Web site (http:www.acr.org) were passed by the ACR council, and are an affirmation of the particular needs for interventional radiology.

You took a sabbatical to work at the FDA. How did your experience working at the FDA impact your practice of medicine and your view of the medical device industry? It was an interesting period. I went to the FDA because I wanted to do something different. At that time, there were a lot of complaints about how devices took a long time to gain approval.

After I received clearance by the FDA, I started looking at some of the submissions. One of the things that I found was that for all hue and cry about why it was that we didn't have devices here in the US, a lot of it had to do with us—"us" being the physicians, as well as the device companies.

Many of the device manufacturers were very small companies, particularly the ones with the more unique devices. They were basically start-up companies and had no idea about the FDA process and not really much of a clue about clinical trials. What tended to happen was that they would send in these proposals that weren't well thought out. There would be a whole back-and-forth process between the agency and the people who wanted to conduct the trial, which tended to frustrate everyone.

Another problem that even continues now was that, although it is and has been available, most of the companies don't take advantage of the fact that you can actually call the FDA and ask them to have a pre-IDE meeting, which is where you come in and explain to the FDA what your product is, how it works, and what you

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would like to do with it, and then how you would propose testing it. They will then talk to you about what they see as being the issues. The companies can also bring in the physicians who are working with them. This seems to be an underused approach, which is unfortunate. Many times, the FDA (which often has considerable sophisticated knowledge about devices) has some questions or comments that really require a physician-user's opinion. When there was no physician present, the questions often went unanswered, and there seemed to be a disconnect between the FDA and the company.

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Another problem was that, unfortunately, a lot of physicians who are supposed to be the investigators just didn't perform their administrative tasks very well. A trial would be set up, it would have the inclusion/exclusion criteria, and then the investigators would decide to use the investigational device in patients outside of the specific inclusion criteria, would break the protocol, and sometimes not even collect the data accurately or completely. The FDA is then in this terrible quandary of having a study that was done with a fair number of patients enrolled, but the data were haphazard and not collected nor documented well.

The FDA works very hard to get devices and drugs out. So, you test the device or drug in what you think is a specific population with specific indications and for specific use, do the best you can, receive the data, and say it looks like it's safe in this population. Then, the device (or drug) gets released, and physicians decide they are going to use it wherever they feel like using it. At this point there may be problems, and Congress and the public complain about how we have unsafe devices and how the FDA let this happen.

There is this enormous pendulum that tends to swing in a 6- or 7-year cycle in which we go from people saying we have all these unsafe devices and drugs to the FDA tightening up and everybody screaming, "Europe has all these great devices and drugs that we don't have!" Unfortunately, as a society, we have to recognize that nothing is absolutely safe and there are risks—there are hopefully benefits, but there are always risks. Everyday there are situations when good people are honestly trying to help patients, but in some cases we end up making things worse. The only way not to have risks with procedures is to not perform them at all. It is the same thing with drugs and devices—the only way not to have problems from a drug or device is not to use it at all.

You were involved in the UA Fibroid Registry. How did that come to be and what was your experience? I initially got involved in fibroids because a patient who had heard about uterine artery embolization was sent to me by one of our gynecologists. I was a bit skeptical because as interventional techniques come, they also tend to go, and some things don't quite pan out the way you anticipate they will. At that point, there were few data about the procedure. A conference about fibroid embolization was being held in London, and I went to it. At the end of the conference, John Reedy, MD, graciously invited people to his hospital to watch him do a couple of procedures. The procedure turned out to be a very straightforward embolization, and I went home and began incorporating it into my practice.

As the procedure started gaining interest, members of the SIR realized that to have credibility, there had to be data, and the registry was started. I think that everyone working in this field owes an enormous thanks to James Spies, MD, Robert Worthington-Kirsch, MD, Scott Goodwin, MD, Jean Pierre Pelage, MD, and others who had the vision to start this registry and spent enormous time and effort on making it a reality. This registry is extremely powerful because of the number of patients enrolled and the quality of the data, and we have all benefited from it.

Is there a possibility for the beginnings of a turf battle between OB/GYNs and interventional radiologists treating fibroids? I have not experienced that, but I do think there are going to be interesting times, because now there is not only intrauterine artery embolization, but there are multiple techniques that can be used to treat women. There is traditional hysterectomy, myomectomy, hysteroscopic myomectomy, laparoscopic myomectomy, laparoscopic hysterectomy, uterine artery embolization, MR-guided, focused ultrasound, a newer medical therapies that are on the horizon. I think the real issue is that we are going to have patients who will be almost overwhelmed with the number of choices they have for treating their fibroids. ■